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CX 2014 audience recognises the impact of drug-eluting balloons

The voting results at the Charing Cross Symposium 2014 (5–8 April, London, UK) captured a powerful shift in audience perception regarding the value of drug-eluting balloons in peripheral arterial disease. Just two years ago, a poll identified that 27% viewed drug-eluting balloons as an alternative to stents; in 2014, 72% now do so. The same session saw the first-ever presentations of 12-month results of the IN.PACT SFA and ILLUMENATE trials, both of which were positive for drug-eluting balloons, and an update on the LEVANT 2 trial.

Voting questions from previous years were presented again this year, in order to assess the clinical views of audience members with regard to drug-eluting balloons. The results then captured the data on the year-on-year shift in perception towards these devices, and indeed the phenomenon of drug elution itself. The audience response polls revealed that nearly 90% voted that drug-elution was worthwhile in the superficial femoral artery. Last year, just 57% cast their vote stating that drug-elution was worthwhile in this anatomical region.

Roger Greenhalgh, London, UK and chairman of the symposium, noted that the voting trends likely reflected the multidisciplinary nature of the meeting itself as the audience members and faculty are composed of the leading vascular surgeons, interventional radiologists and interventional cardiologists.

Two years ago, when delegates at Charing Cross 2012 were asked what the role for drug-eluting balloons was, 27% voted that they were an alternative to stents; 33% voted that they should be used for in-stent restenosis; 19% voted that they should be used as a last resort and 21% voted that they had no role. Now in 2014, 72% voted that drug-eluting balloons are an alternative to stents; 21% voted that they should be used for in-stent restenosis; 3% believed that they should be used as a last resort and 4% voted that they had no role at all.

Gunnar Tepe

There was a similar swing in opinion regarding the cost-effectiveness of drug-eluting balloons. In 2011, 75% of voters stated that they did not find drug elution cost-effective in the superficial femoral artery and only 25% voted that they did. Yet in 2014, 67% said, yes, drug elution is cost-effective in the superficial femoral artery and 33% said it was not.

The voting also revealed a sharp shift seen in favour of

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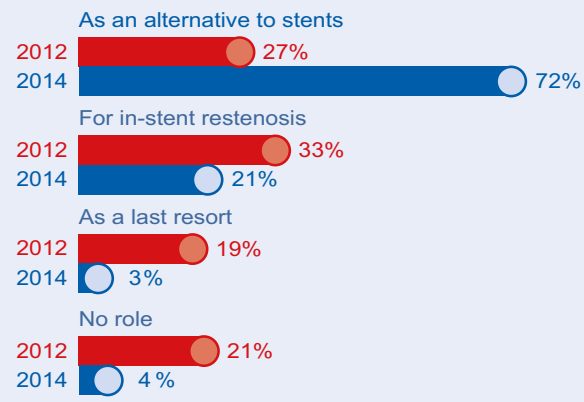
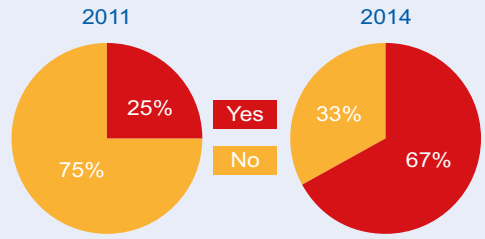
VOTING RESULTS

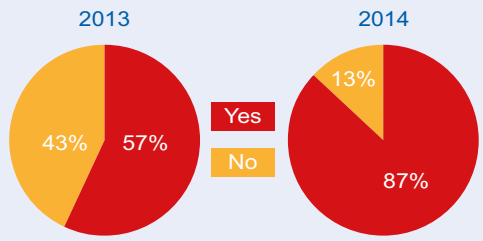
What is the role for drug-eluting balloons?



Do you find drug elution cost-effective in the superficial femoral artery



Drug elution is worthwhile in the superficial femoral artery



No type I and III endoleaks with the Incraft system for EVAR at two years

At the Charing Cross Symposium, Giovanni Pratesi (Florence, Italy) reported that the two-year results of the INNOVATION study confirm the "very promising results" of the one-year outcomes of the Incraft bifurcated stent graft system (Cordis) as they showed that the system was not associated with any endoleaks at two years in patients undergoing endovascular aortic aneurysm repair (EVAR).

Pratesi stated that the Incraft system has been designed to overcome the limitations of current stent grafts for the management of abdominal aortic aneurysms. He commented that it has an ultra-low profile delivery system and the ability to be "customised during the procedure thanks to the bilateral in-situ length adjustment features". Also, according to Pratesi, the graft offers the possibility of covering a wide range of anatomies with a minimum number of product codes.

The aim of INNOVATION (A multicentre, open-label, prospective, non-randomised study of the Cordis Incraft system in subjects with abdominal aortic aneurysms) was to assess the safety and efficacy of the Incraft system for the management of aortic abdominal aneurysms. The primary endpoint was technical success at one-month and the one-year safety endpoints included the absence of device- or procedure-related major adverse events, absence of type I or III endoleaks and maintenance of device integrity through one-year of follow-up. The main inclusion criteria included a

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CX 2014 audience recognises the impact of drug-eluting balloons

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drug-eluting balloons from last year. In 2013, 57% of the delegates voted that drug elution was worthwhile in the superficial femoral artery, while 43% believed that it was not. In contrast, in 2014, an overwhelming 87% agreed with the proposition "drug elution is worthwhile in the superficial femoral artery" while 13% did not.

The voting followed the first-ever presentation of 12-month data from the randomised multicentre IN.PACT SFA trial, which revealed that treatment with the IN.PACT Admiral drug-eluting balloon (Medtronic) was significantly superior to percutaneous transluminal angioplasty on several fronts. The trial results showed that clinically driven target lesion revascularisation rates were significantly lower with the drug-eluting balloon as compared to those achieved with angioplasty (2.4% vs. 20.6%, p<0.001). Similarly, the primary patency rate achieved with IN.PACT Admiral was 82.2%, while the primary patency achieved with angioplasty was 52.45% (p<0.001).

The IN.PACT SFA trial enrolled 331 patients at 57 sites across Europe and the USA and patients were randomised to either receive treatment with a drug-eluting balloon or percutaneous transluminal angioplasty. To ensure data accuracy and reliability, patency endpoints underwent evaluation by an independent imaging core lab, while all clinical events were adjudicated by an independent clinical events committee. To prevent bias, both the imaging core lab and the clinical events committee were blinded to the patients' randomisation.

The two cohorts were well-matched with regard to baseline patient demographics. Nearly all of the patients had moderate or severe claudication and approximately 5% suffered from rest pain because of more advanced disease. Other baseline characteristics including diabetes (40.5% vs. 48.6%) and hypertension (91.4% vs. 88.3%), and mean lesion length (8.94cm vs. 8.81cm) and percentage of total occlusions (25.8% vs. 19.5%) were also similar between the two groups.

Gunnar Tepe, Rosenheim, Germany, presented the 12-month results of the trial and noted that there was robust level 1 evidence to show that the IN.PACT Admiral drug-eluting balloon had shown the lowest target lesion revascularisation and highest patency rates ever reported. He added primary patency at one year was calculated by Kaplan-Meier survival estimates and was 89.8% for the drug-eluting balloon group and 66.8% for the angioplasty group.

ILLUMENATE and LEVANT 2

Positive 12-month results of the ILLUMENATE study were also presented at the international symposium for the first time, and provided a further boost for drug-eluting balloons.

Patrick Peeters, Dendermonde, Belgium, presented the results of the study, which found that the 12-month, first-in-man outcomes associated with the use of the Stellarex (Covidien) drug-eluting balloon in patients with superficial femoral and/or popliteal lesions were comparable to the best published 12-month outcomes associated with other drug-eluting balloons.

Peeters reported that the aim of the first-in-human study was to establish the safety and effectiveness of the device and that the study had two arms. The 50 patients in cohort A underwent predilatation before treatment with the drug-eluting balloon. The 30 patients in cohort B underwent treatment directly with the drug-eluting balloon without predilatation.

To be included, patients had to either have a *de novo* or restenotic lesion (≥30mm and ≤150mm) with a target vessel reference diameter between ≥30mm and ≤70mm in the superficial femoral or popliteal artery artery. Lesions could be treated with a maximum of two drug-eluting balloons. The study endpoints were major adverse events (death, target lesion revascularisation, amputation) at six months, 12 months, and 24 months, binary restenosis and late lumen loss at six months, and primary patency at six months, 12 months, and 24 months. Twenty six per cent of patients in cohort A and 23% in cohort B had target lesions that were ≥100mm.

In both cohorts, procedural success was 100% and the rate of major adverse events was 10% at 12 months—Peeters stated that there were "no safety concerns to date in either treatment cohort". The primary patency in cohort A was 92% at six months and this went down to 87% at 12 months. Furthermore, the 12-month target vessel revascularisation rates in the PACIFIER, LEVANT I, and THUNDER trials (which all assessed paclitaxel-eluting balloons) were 8.1%, 28.9%, 10.9%, respectively compared with 10% [for both cohorts] for the ILLUMENATE study. Peeters added that the 12-month primary patency rate for cohort B was not available because clinical, angiographic and Doppler ultrasound assessment was still ongoing.

He concluded that "the device is safe with durable results at the 12-month follow-up. The results are comparable to the best published drug-eluting balloon results to date. The ongoing follow-up for the second cohort may provide comparable results." He added that larger, multicentre trials comparing the balloon with percutaneous transluminal angioplasty were underway.

Then, Dierk Scheinert, Leipzig, Germany, followed up with the discussion of data and study design of the LEVANT 2 trial, a prospective, multicentre, single blind, randomised, controlled trial comparing the use of the Lutonix (CR Bard) drug-eluting balloon with standard balloon angioplasty for treatment of femoropopliteal arteries.

"LEVANT 2 is a rigorous trial designed to reduce bias. Our protocol had controlled pre-dilatation prior to randomisation to limit the number of bail out stents and in the trial design, we did not count bailout stenting as target lesion revascularisation. Clinicians are blinded to the Doppler ultrasound results and the six month data are promising regarding safety and efficacy," Scheinert said.

No type I and III endoleaks with the Incraft system for EVAR at two years

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proximal neck length of ≥15mm and up to 27mm in diameter, an access vessel large enough to accept the 14F outer diameter of the delivery catheter, and an aortic bifurcation >18mm in diameter.

The rate of technical success at one month was 97% (56 of 58 patients of the original 60 patients who were enrolled) and the rate of freedom from aneurysm enlargement was 100% at one year with the absence of both type I and III endoleaks in all patients.

Pratesti reported that two-year results confirmed these "very promising" early and one-year outcomes. He added that (at two years): "There were zero incidences of endoleaks (type I or type III), device- or procedure-related major adverse events, stent-graft migrations, or stent fractures." He further said that there were also no incidences of aneurysm sac enlargement with sac shrinkage being observed in 45% of patients. However, one patient did develop a late limb occlusion at day 666 due to sac contraction and limb conformation change.

Pratesi concluded: "These excellent results are encouraging and suggest that the Cordis abdominal aortic aneurysm stent graft is a valuable alternative device with increased applicability over the broad spectrum of aorto-iliac anatomic configurations encountered in patients undergoing EVAR."

Data pave the way for future CE marking

In a Cordis Satellite Symposium also held at the Charing Cross Symposium, Jan Brunkwall, Cologne, Germany, spoke to delegates about the Incraft clinical programme. He said that INNOVATION, which was the first-in-man study, was initiated in 2010 and enrolled 60 patients in Germany and Italy. Next in the clinical programme timeline was the INSPIRATION investigational device exemption, started in 2012, which enrolled 190 patients in the USA and Japan. Further to these trials, the INCEPTION post-market study is expected in the near future, including 150 patients in Europe.

Giovanni Pratesi

He spoke about the data from the INNOVATION study and added that another study, the INSPIRATION trial, showed freedom from endoleaks type I, III, IV was 100% (189/189) and stent graft patency was also 100%.

Brunkwall said that in the Incraft's clinical programme timeline, the CE mark is expected in mid-2014 and post-market approval is expected in the second quarter of 2015.

Concluding his presentation, he said: "Initial global experience and mid-term European results with the next generation customisable, ultra-low profile abdominal aortic aneurysm stent graft system are encouraging."

Luca Bertoglio, Milan, Italy, said in the following presentation: "Incraft was engineered to address the unmet needs of current endografts by combining unique features and refinements compared to existing endografts. His presentation was on the technical features of the Incraft stent graft system.

"The Incraft is a bifurcated endovascular graft characterised by a trimodular configuration with a flexible, integrated delivery system," he said.

With the introduction of partial proximal repositioning, in situ length adjustment and by having an ultra-low profile fully laser-cut stent design, the endograft aims for high deliverability and placement accuracy in a durable and easy to use system with broad anatomical coverage, Bertoglio stated.

"Encouraging mid-term clinical results with patients in up to four years of follow-up along with extensive bench-top testing suggest that the Incraft lives up to its promises," he said.

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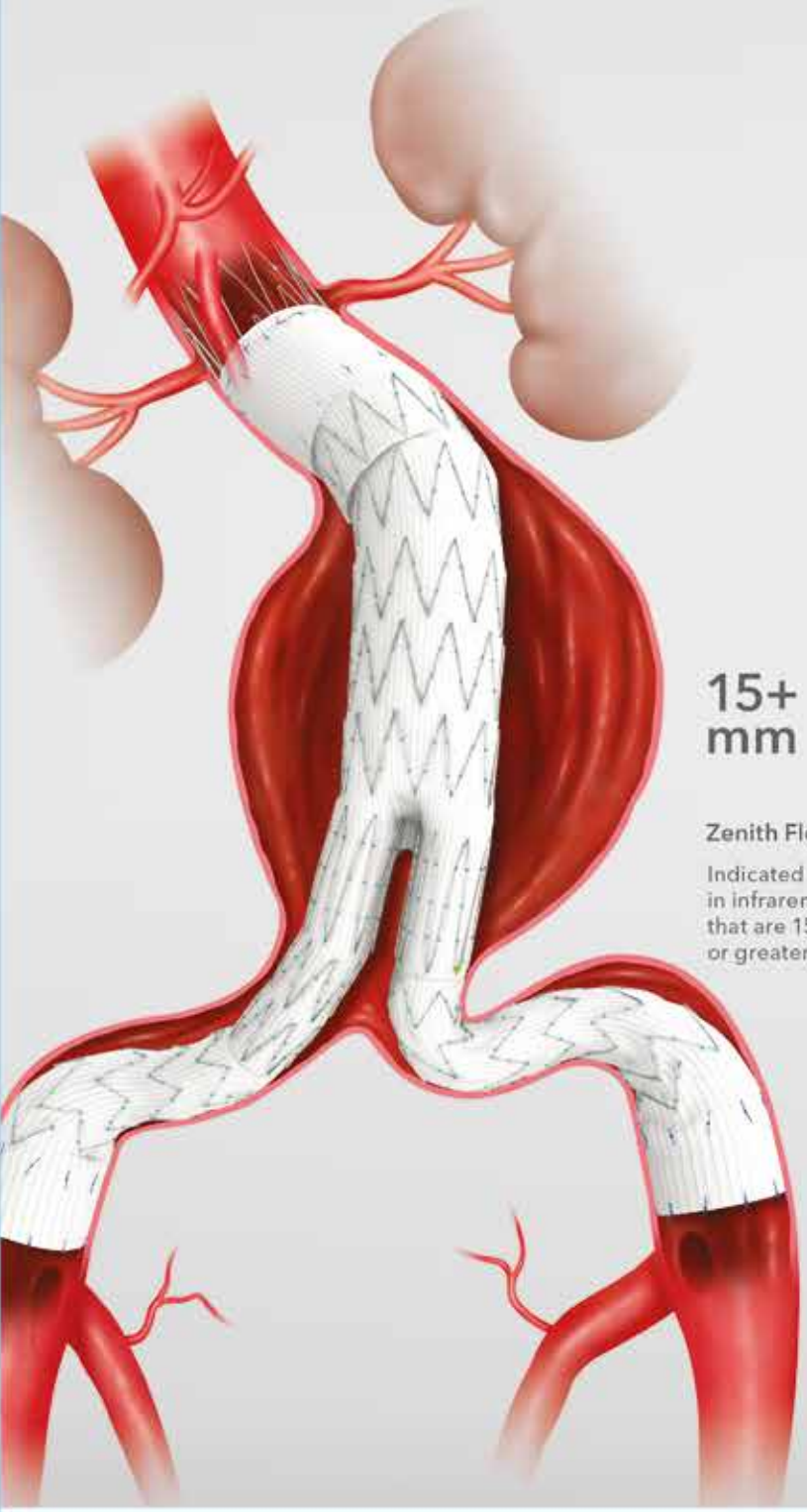

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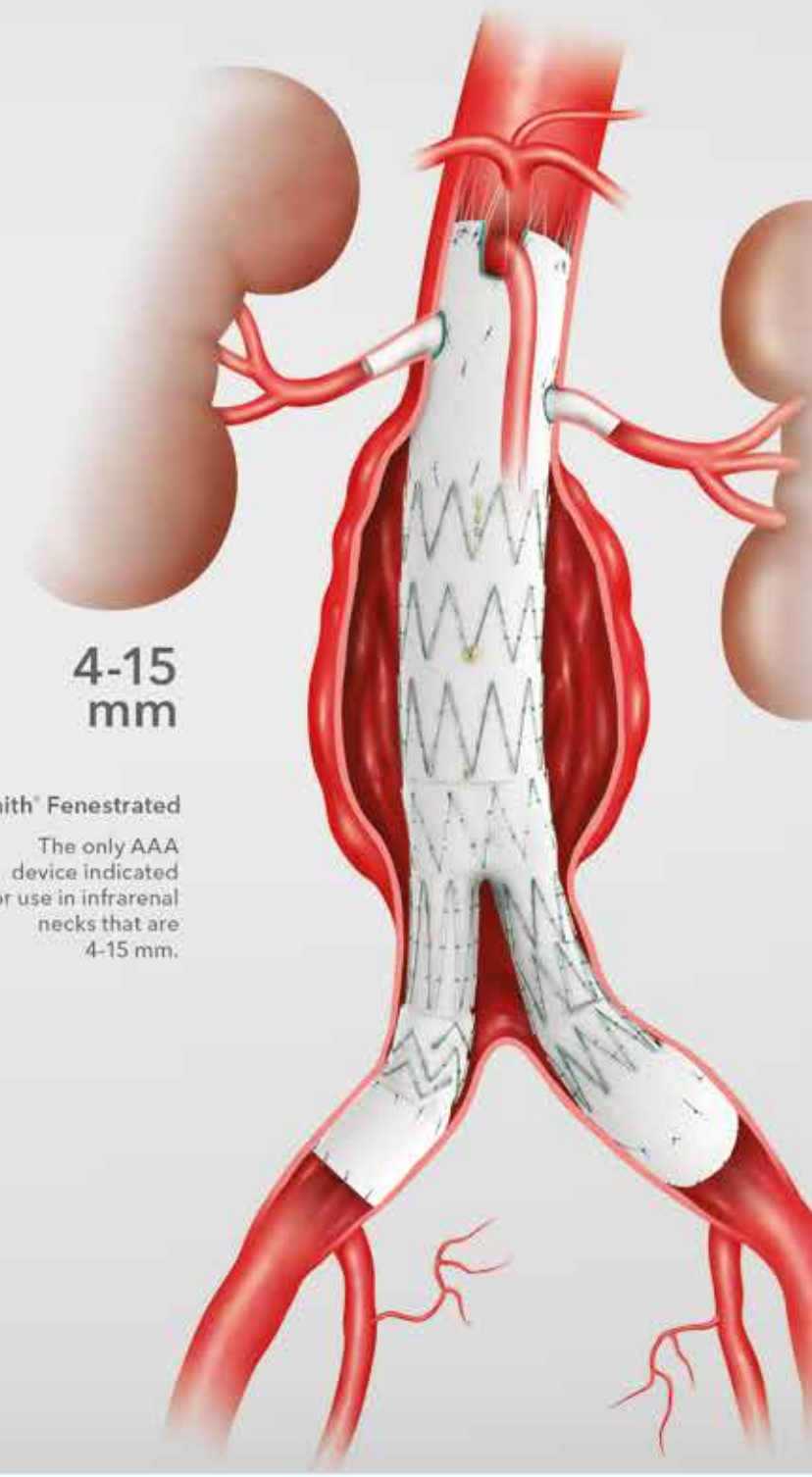

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Alarming lack of physician awareness about radiation hazards exposed

A session held at the Charing Cross International Symposium (5–8 April 2014, London, UK) revealed that there is a lack of physician awareness about the dangers of radiation in the interventional suite. The effect of exposure to radiation has become particularly important with the widespread use of endovascular procedures, and delegates heard how no single specialty had a monopoly on bad practice when it came to radiation.

During the session it became apparent that the knowledge base about radiation has taken time to be developed and incorporated into training, and that appropriate behaviour in the interventional suite was often ignored, leading to operators receiving unnecessary doses of radiation. , Interventional radiologists, surgeons, interventional cardiologists and radiologists are all guilty of bad practice, delegates heard.

Lindsay Machan, Vancouver, Canada, who was invited to comment on the Radiation Exposure session, told delegates that there were "two dirty little secrets" about radiation that he wanted delegates to pay attention to. "The first is that there is no safe dose of radiation; the idea that there is a threshold has now been debunked. The second is that every person in this room has a variant level of the radiation repair genes and there is no test as yet for the repair genes."

Machan referred to the results of a long-term international study of thousands of workers exposed to radiation in the Chernobyl disaster in 1986, which found that the disaster clean-up crew, no matter where they were located, had the same incidence of cataracts, dispelling the idea of there being a threshold for cataract development. Referring to the outcomes from another 20-year study published by Chodick *et al* in the *American Journal of Epidemiology* in 2008 that found that there was no apparent threshold level for technologists to get cataracts, he said: "Everything that you hear about thresholds is absolutely not true. Treat radiation like iodinated contrast and use only as much as needed and no more."

Machan also told delegates about the work of the late Basil V Worgul, New York, USA, which had shown that there was a possibility that the human population included genetically predisposed radiosensitive subsets.

Lindsay Machan

"Everybody in this room has some degree of radiation damage and not everyone has complex innovations available to help them reduce the dosage. However, the distance from the tube and the importance of magnification [that result in bigger radiation doses] cannot be overstated," Machan said.

Operator behaviour is driven by various factors

"A real time reminder of the dose is important. Another important thing that we have observed is that when our nurses and technologists became aware of their own risk, it has changed the dynamic quite considerably. Operators are driven by a different dynamic; we want to get that procedure done, we want to show the photos and have a tendency to ignore [the radiation dose] and the consequences, as they might be 20 years away. While I am in no way being misogynistic, there is a certain machismo about it. However, usually the nurses and technologists are not [driven by the same things]. They are there to do a job. As soon as they realise that they are at risk, it has an amazing impact. They start pointing out the fluoro time, question where they are asked to stand, and if you are doing a pedal puncture they might not stand behind the foot and hold the foot for you," Machan said.

Another member of the audience made the point that they had measured and found that the radiation exposure was less in the hybrid suite as compared to their previous set-up. Their team had also found that the operator steps away just 6% of the time during digital subtraction angiography turns and have been working on educating the entire team. The awareness is lamentable, delegates heard.

Patients suffering burns

"One of the problems is that radiation burns can occur several months after the procedure and often the patient does not connect that to the procedure. Also, due to the fact that the image intensifier is above them, they think that the radiation dose is there. They do not realise why they have a burn on their back and often go to see a physician who does not have radiation in their mind as the cause, so there is a gross underreporting of the problem," Machan said. The panel also commented that the biggest risks were for health professionals, as they are exposed repetitively during the course of their work. The maximum exposure resulted when branched devices were implanted, and the biggest risks are for health professionals as they are exposed every day.

Is regulation around the corner?

Machan made the point that while the health effects of radiation were one aspect, another issue was that of looming regulation for radiation workers. He pointed to the current practice in some US hospitals of radiation workers "sitting it out" if they had a high reading on their dosimeters. The sit-out period could range from anywhere between a week and a month. "Think of what this would do to your endovascular practice," urged Machan. "If you have to sit out for a month every couple of months, you cannot actually practise."

The panellists noted that while there was a wide variation in education and training requirements for personnel to be able to use radiation, there was need for special education for the whole team on to behave in an operating room. Machan also noted that while there were well laid-out and appropriate guidelines in place, there was a bigger problem was with adherence and enforcement.

Johannes Gahlen, Ludwigsburg, Germany, who spoke on the importance of radiation dosage exposure to patient and operator, said: "It is vital to adhere to the ALARA principle of keeping the dose as low as reasonably achievable. It is important to decrease the beam time, keep your distance from the system, use protective shielding, instruct the team, collimate the field of view, reduce the frame rate use use low dose programmes," he said.

Donation to the Circulation Foundation

The charitable foundation of the Vascular Society of Great Britain and Ireland, the Circulation Foundation, was presented with a £3,000 donation from the Charing Cross Symposium and the CX Office-based Vein Practice Course at the symposium.

The Circulation Foundation is the only charity dedicated to vascular health and the Foundation relies on donations to fund vital research.

"We are delighted that the Circulation Foundation is the chosen charity of the Charing Cross Symposium and it is a great pleasure to present this cheque on behalf of the CX Office-based Vein Practice Course and the Charing Cross organisers. We are very grateful to Professor Greenhalgh and the Charing Cross organisers," said Ian Franklin, chairman of the Circulation Foundation and director of the CX Office-based Vein Practice Course.

Michael Wyatt, president-elect of the Vascular Society of Great Britain and Ireland, accepted the cheque on behalf of the Circulation Foundation.

Michael Wyatt and Ian Franklin

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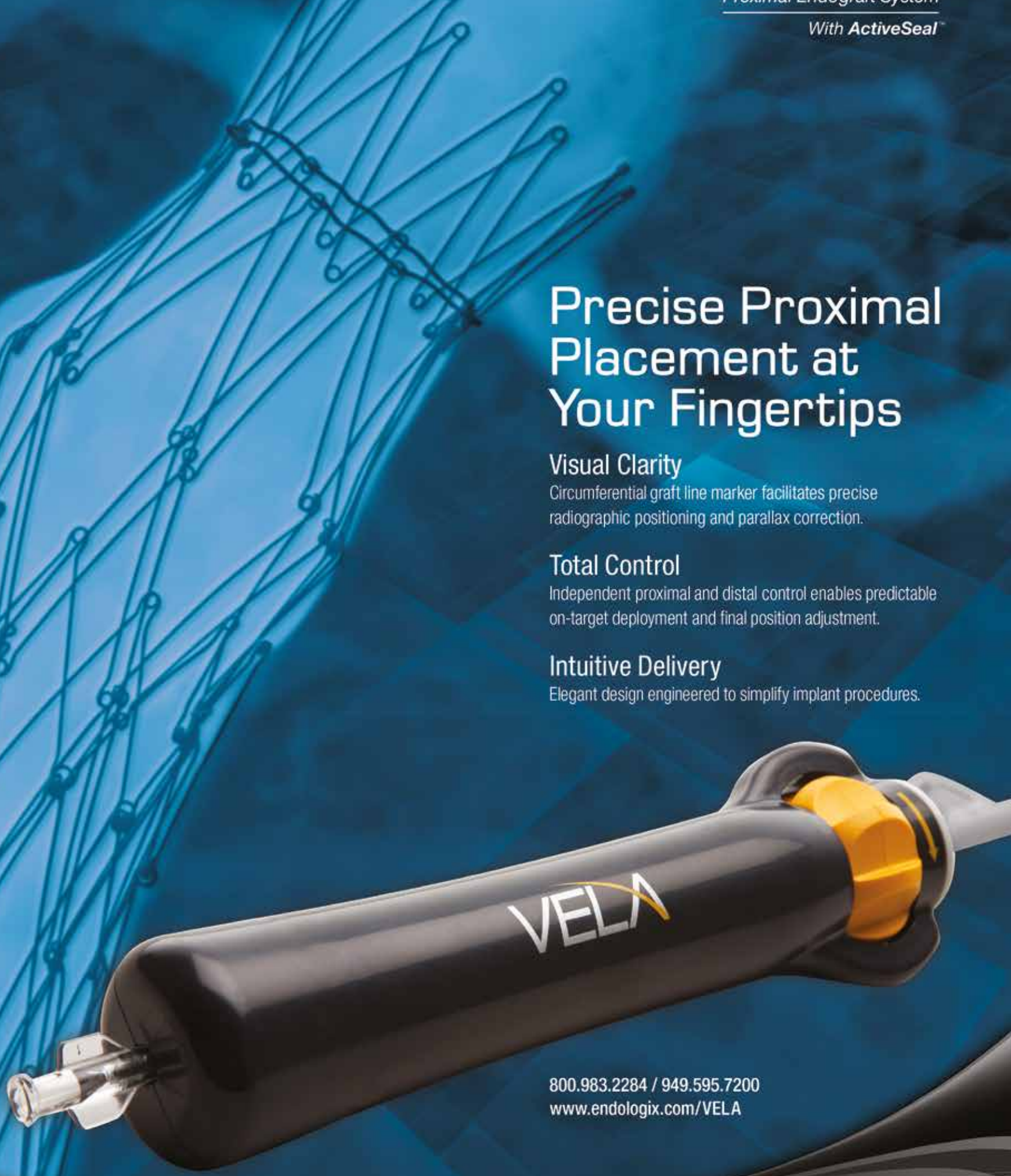

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Intravascular imaging important to manage blunt aortic injury appropriately

At the Charing Cross Symposium (5–8 April 2014, London, UK), Benjamin Starnes told the audience attending a mini symposium on acute aortic transection that intravascular ultrasound (IVUS) was an important tool in the management of patients with blunt aortic injury undergoing thoracic endovascular aortic repair (TEVAR) because it helps to ensure accurate sizing of the endograft and prevent device-related complications. The session also reviewed the differences between image-based classifications of blunt aortic injury.

Starnes, who is a professor of surgery and chief of the Vascular Surgery Division, University of Washington, Seattle, USA, reported that, over the past decade, endovascular repair of patients with blunt traumatic aortic injury has become the "predominant approach to fixing these injuries", but added that there were "unique challenges" to using the endovascular approach. He said: "One of challenges is the dynamic nature of the aorta. There are some interesting data from blood-letting studies in Yorkshire pigs that show significant decrease in aortic diameter accompanying induced haemorrhagic shock, with a dose-dependent effect."

According to Starnes, aortic diameter is also known to increase after resuscitation and the area with the greatest change in size is the area that is most commonly injured in blunt trauma (ie. the isthmus and descending aorta). He added: "CT angiography is used for diagnosis of these injuries and axial slices from the initial scan are often used for planning and sizing of the repair. While using IVUS at the actual time of repair to better characterise the injury, we noticed a difference in the aortic diameter with systolic variation [compared with the diameter observed on the initial CT angiography]. This then begs the questions "Is initial CT angiography appropriate for sizing the endograft in these patients?" and "Is that endograft going to be undersized once that patient is fully resuscitated?"

Starnes and his colleague, Nam Tran, therefore conducted a retrospective chart review of patients with blunt aortic injury who underwent TEVAR at their level-one trauma centre to determine if there was a difference between the aortic diameter observed on diagnostic CT angiography and that observed on IVUS at the time of the repair. The inclusion criteria were initial admission or pre-admission CT angiography, IVUS at the time of repair, and a post-implant CT angiography. Of the 26 patients who were treated at the centre during the study period (July 2007–July 2011), three patients did not have post-implant CT angiography information, one patient was converted to surgery, and six patients did not receive IVUS—leaving 16 patients available for assessment.

Benjamin Starnes

There was a significant difference of 2.4mm between mean aortic diameter with initial CT angiography and mean aortic diameter with IVUS: 21.7mm vs. 24mm, respectively (p=0.004). Starnes noted: "When we look at post-implant CT angiography compared with initial CT angiography, there is again a highly significant difference of 3mm (p=0.0001). But, when we compared post-implant CT angiography with IVUS, there was no difference." He added that when they reviewed theoretical graft diameters, there was a significant difference of 2.4mm (p=0.003) between the size of the graft that would be chosen based on the initial CT angiography and that based on IVUS at time of repair. There was also a significant difference in graft size between post-implant CT angiography and initial CT angiography (3mm; p=0.0002), but no difference in size between post-implant CT angiography and IVUS.

"I believe IVUS is a critical and important tool for the management of patients with blunt aortic injury, especially if no repeat CT has been performed prior to definitive repair," Starnes concluded.

> ***"I believe IVUS is a critical and important tool for the management of patients with blunt aortic injury, especially if no repeat CT has been performed prior to definitive repair"***

Ali Azizzadeh (Houston, USA) also presented data at the mini symposium, reviewing the long-term effects of intentional stent graft coverage of the left subclavian artery (in patients with blunt aortic injury undergoing TEVAR). He said that in a review of 82 patients undergoing TEVAR at his centre between September 2005 and July 2012, 50 received intentional stent graft coverage of their left subclavian artery. Azizzadeh reported: "Intentional coverage of the left subclavian artery during TEVAR for blunt aortic injury appears safe without compromising mental or physical health outcomes. Furthermore, left subclavian artery stent coverage does not increase the long-term risk of upper extremity symptoms or impairment of normal activities."

Does intramural haematoma exist?

As well as presenting data for the role of IVUS in the management of patients with aortic injury, Starnes also reviewed the classification of the injury. He reported that he and his colleagues developed a new image-based classification system for these types of injuries because they believed the current classification system, adopted by the Society for Vascular Surgery (SVS), was "lacking". Starnes explained: "The SVS system has four grades of injury—grade one, intimal tear; grade two, intramural haematoma; grade three, pseudoaneurysm; and grade four, rupture—but does not provide for any treatment recommendations because grades two through four are treated the same way and we do not believe that grade two actually exists. In a review of 140 aortic transections at our centre, we did not see a single case of intramural haematoma."

Therefore, they developed a new classification system based on the presence or absence of an aortic external contour abnormality. Under this new system, intimal tear (intimal defect and/or thrombus of <10mm in length or width) and large intimal flap (intimal defect and/or thrombus of ≥10mm in length or width) were placed in the absence of an aortic external contour abnormality category while pseudoaneurysm (contained rupture) and rupture (free contrast extravasation or haemothorax found upon thoracotomy) were put in the presence of an aortic external contour abnormality category. Starnes noted that, in a review of 36 patients with minimal aortic injury at their centre, no patient with a normal external contour of the aorta died of their injury and added that "absence of external aortic contour abnormality may be useful in selecting patients for non-operative management."

However, Michael Dake (Stanford, USA) commented that there was a lack of consensus surrounding intramural haematoma as unlike Starnes and colleagues, Rabin and colleagues did recognise the existence of intramural haematoma and classified it as being a "grade one" injury (in contrast to the SVS classification). He added that Osgood and colleagues, in an another system, classed intramural haematoma as being "grade 1B" but he noted that they did not find any patients with that type of injury in their series. Dake reported, regardless of how it was classified, recent publications have suggested that: "Intramural haematoma without associated peri-aortic component, contour abnormality, or pseudoaneurysm may be conservatively managed with appropriate follow-up imaging."

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Frank B Cockett dies at age 97

Frank Bernard Cockett died on 17 January 2014 at the age of 97. He was a general and vascular surgeon at St Thomas' Hospital London and a founding member and former president of the Vascular Surgical Society. Cockett was known for his substantial contributions to vascular surgery research with his work on the pathology and surgery of venous disease.

Cockett with his wife Dorothea and their twins in 1966

Joining the RAF

At St Thomas' Hospital in 2007

On Saphena with Bobby Haycock in 1965

Born in Australia and living his early years in Tasmania, Cockett moved to England in the 1920s when his father, a congregational minister, took up office in Bedford. He was educated at Bedford School and then the City of London School for Boys before winning a scholarship to St Thomas' Hospital Medical School where he gained first class honours BSc in physiology before qualifying in medicine just before the outbreak of war. He became a house surgeon at St Thomas' Hospital in 1940 and was resident during the time the hospital was bombed with severe damage and loss of life. Throughout the month of the Blitz he was one of a small band of less than 10 doctors who kept the largely evacuated hospital open for the emergency treatment of the injured public. Operating day and night in makeshift theatres in the basement of the hospital, where he also slept, he wrote contemporary descriptions of his experiences in letters home. These were later published in a book titled "The War Diary of St Thomas' Hospital 1939–1945".

In 1942 Cockett joined the Royal Air Force, serving abroad as a Squadron Leader mainly in Malta and Gozo. This period of his service life was later described in his book "The Maltese Penguin". He was later posted to Italy before spending his final months in uniform in Algiers.

Cockett married Felicity Fisher in 1945 and the following year he returned as a civilian to a junior surgical post at St Thomas' before becoming senior lecturer in surgery. In 1958 Felicity died tragically in a car accident, leaving him and three children. Cockett later married Dorothea Newman in 1960 and had two further children.

His main contribution to vascular surgery began in 1950 soon after taking over the leg ulcer clinic at St Thomas', recognising an "enormous unsolved problem". During numerous painstaking dissections on cadaver limbs, including the new technique of arterial and venous injections, he learnt that the ankle perforating veins, and not the saphenous vein, were the direct venous drainage pathways of the ulcer bearing area in the lower leg. He found that the ankle perforating veins were occasionally enormously enlarged, and in 1951 operated on his first case with considerable trepidation that the wound would not heal. By 1953 he had operated on a series of cases and published "The ankle blowout syndrome" in The Lancet with D E Elgan Jones. He was also interested in venous compression syndromes, and published widely on anatomical compression of the left iliac vein. His major textbook, written with Harold Dodd, "Pathology and Surgery of the Veins of the Lower Limbs" went through two editions in 1956 and 1976.

A keen sportsman, Cockett enjoyed squash, swimming, skiing and above all, sailing. He owned a series of boats culminating in a steel-hulled ocean racing yacht named Saphena, and its dinghy Varix. Generations of students and junior staff will recall crewing with him on this boat.

Retiring from his NHS consultancy in 1981, Cockett continued in private practice for a number of years but he became increasingly interested in another love—marine art. He haunted the auction rooms between clinics getting to know the dealers and adding to his personal collection of marine paintings. He became an authority on early English marine paintings and a much esteemed advisor to Christies. In 1993, Cockett was involved in a serious motor accident which left him less mobile, but with time to collate his expertise and publish a book titled "Early Sea Painters 1660–1730" which chronicled the rise of marine art in England.

Similarly, Cockett was also absorbed by the history of St Thomas' Hospital. He was a founding member of the St Thomas' History and Works of Art Committee, serving as its chairman for 12 years, and published regularly in the St Thomas' Hospital Gazette.

Cockett is survived by his wife, Dorothea, and all five of his children.

"This man has been and remains an inspiration"

ROGER GREENHALGH

COMMENT & ANALYSIS

Frank Cockett, "Ace" as we thought of him, was my inspiration to be a vascular surgeon. At St Thomas' Hospital from 1963 onwards, first as a clinical student (and oarsman in a Cambridge intake), it was at once clear that this man had an international reputation. To a student, therefore he might appear remote but he was not. He would readily allow the clerking of his patients and then to have the privilege of giving the findings to him. This led to personal coaching.

"Ace" was fascinated with every type of boat and the St Thomas' Light IV was no exception. Later he was to reveal to me that he had followed my final race at Henley Royal Regatta and "whenever I replay it you always lose the race".

"Ace" had a host of vascular surgeons and specialists at his funeral this year. "I do not want a memorial service—they will have forgotten me," he repeatedly said to his family. So an "extended family funeral" was rapidly arranged. Just about all of the family from all over the globe dropped everything and came. So did the vascular surgeons and specialists who "Ace" had trained. Whatever was booked to be done, it was dropped. "Ace" came first—he always did—effortlessly impressive. His "Ace boys" loved being together once more and felt his influence upon us again.

The Cockett family loved skiing and came to a vascular ski group and Karin and our children, Stephen and Christina, were there of course. It was in Austria and "Ace" found a comment by Stephen very funny indeed as it was at my expense and justly so. "Ace" later commented that Stephen had said "Never make a skier that one" and it was said in a total matter-of-fact way. "Ace" loved it.

When the great man lay in an intensive care department on Boxing Day after his car accident, Dorothea Cockett called our home and I left at once. His eyes were closed. The twins and Dorothea were very solemn. The eyes opened: "My God! I must be very sick if you are here". He was back!

What other internationally famous vascular surgeon and family would invite a young surgical trainee, wife and baby to their holiday home near Lymington and Ibiza? Who else would map out what career move to make and when not to return to my beloved alma mater? He was like that to all of us.

Alive and dead this man has been and remains an inspiration for "his boys".

Roger Greenhalgh is editor-in-chief of Vascular News

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Leave nothing behind: Bioresorbable devices are an “exciting prospect” for the future

Andrew Holden, associate professor of Radiology, Auckland City Hospital, Auckland, New Zealand, presented data on the developments in bioresorbable technology at the Charing Cross International Symposium (5–8 April 2014, London, UK). He said that, as drug-eluting balloon data are limited to short and intermediate length lesions, bioresorbable stents or scaffolds are an “exciting prospect” for the future.

Andrew Holden

“The long and mobile femoropopliteal arterial segment is a challenging environment for endovascular intervention; for more complex lesions a scaffold is often required to prevent residual stenosis and flow-limiting dissection. An anti-restenosis strategy is also important, particularly in claudicants where long-term patency is vital,” he noted.

“Drug-eluting balloons are highly promising but have only been studied for any duration in relatively short lesions. Drug-eluting stents have shown satisfactory patencies in intermediate length lesions but suffer the problems of a permanent self-expanding metallic implant.” In order to address this problem with drug-eluting stents, Holden said for many years bioresorbable stents have been eagerly awaited in the superficial femoral artery.

“A bioresorbable stent may provide a scaffold to optimise the acute result after angioplasty without the long-term irritation of a self-expanding stent. Such a scaffold must withstand the hostile environment of the superficial femoral artery, provide mechanical support and integrity through vessel healing, remain biocompatible through resorption and facilitate drug delivery,” he said.

Three bioresorbable stents have recently been studied in the superficial femoral artery. The Abbott Esprit 1 trial used a balloon expandable poly L-lactic acid scaffold in iliac and femoral arterial lesions ≤50mm in length that could be treated by a single 6.0mmx58mm device. The study reported excellent procedural success. Although lesion length was short (mean 35.7mm), the patency data and improvement in Rutherford-Becker status at one year was very encouraging, Holden said.

He also noted that the 480 Biomedical Stanza stent has been studied in the STANCE trial. This flexible, self-expanding stent is a poly lactic-co-glycolic acid and bioresorbable elastomer composite and fully resorbs in 12–15 months. Acute performance and subsequent stent strut encapsulation and resorption has been evaluated with optical coherence tomography (OCT). This study reported excellent procedural success and acute stent performance, treating longer lesions (up to 90mm), according to Holden.

Holden explained that late lumen loss seen in the first cohort of patients was due to a combination of vessel recoil and neointimal hyperplasia. The device was modified in a second patient cohort with minimal vessel recoil. A paclitaxel, drug-eluting version of the scaffold has recently entered the clinic in the SPRINT trial, he added.

He also reported that the Igaki-Tamai bioresorbable scaffold (Remedy, Kyoto Medical) has been used in the superficial femoral artery in a 30 patient cohort. Acute procedural results were very good, as in the STANCE trial, Holden noted.

“Binary restenosis rates at 12 months were unacceptably high and further modifications are planned. Small clinician initiated trials using coronary bioresorbable stents in the tibial arteries are being performed but meaningful results are not yet available,” Holden commented.

“There has been considerable progress with bioresorbable stents in the superficial femoral artery. The technology is not yet ready for routine clinical practice but that exciting prospect should not be far away,” Holden concluded.

BASIL-2 trial launched to compare outcomes after bypass surgery and endovascular intervention in patients with severe limb ischaemia

Andrew Bradbury (BASIL-2 chief investigator, Birmingham University, UK) reported that the UK National Institute for Health Research Health Technology Assessment have funded the randomised controlled trial to compare outcomes following vein bypass surgery and best endovascular therapy in patients with severe limb ischaemia due to disease below the knee.


Andrew Bradbury

Bradbury reminded the audience at the Charing Cross International Symposium that the BASIL-1 trial showed a significant improvement in survival with bypass surgery compared with angioplasty in severe limb ischaemia patients with mainly femoropopliteal disease who survived for two years, but that up to two years there was no difference in outcomes. These and other data have been used to justify “an endovascular first approach” in severe limb ischaemia patients not expected to live more than two years with bypass surgery usually being reserved for better risk patients.

However, he added that BASIL-1 data may no longer be relevant because the trial recruited its patients more than 10 years ago and endovascular technologies have “changed beyond recognition” since then. Interventional radiologists are more skilled, and surgeons are now performing hybrid procedures, he noted.

“The problem, however, is that virtually all of the studies in this field of practice are industry sponsored and primarily aimed at obtaining market approvals,” he said, further adding that as such, they had not produced the answers required by patients, or private and public health purchasers needing to make decisions about which revascularisation strategy is preferable.

Bradbury said that during the development of UK national guidelines for peripheral artery disease, the National Institute for Health and Care Excellence (NICE) had been surprised, even “shocked”, that decisions regarding the management of severe limb ischaemia were being taken on the basis of such a poor and potentially biased evidence base.

In BASIL-2, 600 patients with below-the-knee atherosclerosis, with or without femoropopliteal disease in addition, will be randomised to receive either “best endovascular therapy” or a vein bypass.

Recruitment, which starts in a few weeks will last for 36 months and the average follow-up will be 3.3 years. The primary endpoint is amputation-free survival but a wide range of secondary clinical endpoints will also be collected along with a number of patient reported outcome measures.

Bradbury said that there was an “urgent need” to undertake pragmatic, scientifically robust and publicly-funded randomised controlled trials of surgical and endovascular therapies in severe limb ischaemia that were powered for clinically important endpoints and that included a full cost-effectiveness analysis.

He added that the BASIL-2 would look at the direct health care costs and, for “the first time”, the costs of personal social services. “Without data from such trials, we cannot be sure that endovascular interventions in this patient group are not going to be associated with net harm or suboptimal use of precious health resources,” he said.

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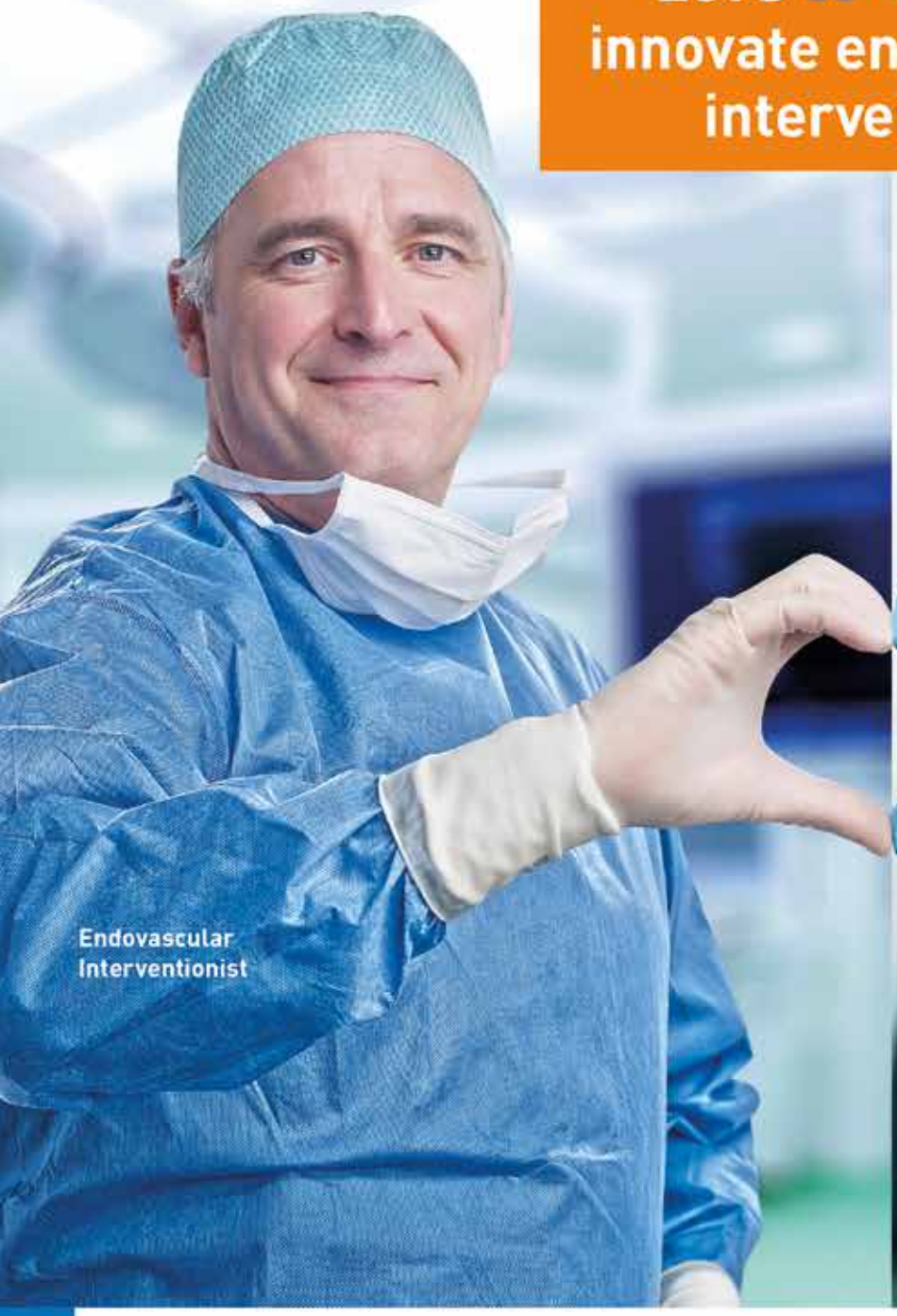

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Early results from subclavian artery branched endoprosthesis studies presented

Michael Dake, Stanford, USA, outlined the first experiences with the Gore TAG (WL Gore) thoracic branch endoprosthesis and Frank R Arko, Charlotte, USA, presented on the MONA LSA (Medtronic) branched device results at a session at the Charing Cross Symposium (5–8 April 2014, London UK). Both speakers shared early cases and their results.

Thoracic aortic aneurysms that involve the left subclavian artery often leave physicians no choice but to use surgical techniques or to cover the branch vessel. "Although reports from single-centre experience with the hybrid approach have been positive, a single branch thoracic endograft specifically designed for treatment of the aortic arch (zone 0–2) could be useful in extending the advantages of endovascular repair to the aortic arch. As such, the Gore TAG Thoracic Branch Endoprosthesis is designed as a modular system which allows for treatment of aortic arch pathologies using a less invasive hybrid endovascular approach," Dake said.

He presented on the zone 2 US investigational device exemption feasibility trial that will enrol 20 to 40 patients at six sites. Patients will be followed for five years. The study will evaluate the device for the treatment zone 2 aneurysms.

The Gore TAG thoracic branch endoprosthesis has a modular construction design with off-the-shelf components. It has an inner lumen for anchoring and sealing the branch component. The complete system consists of aortic and branch components designed for the use in the arch, and also the accompanying accessory devices to facilitate delivery.

"The system is easy to use with a single femoral access and requires minimal catheter manoeuvres. It is safe with zero ischaemic time and has low risk of branch vessel coverage. After the first four cases, successful access and deployment of the endoprosthesis was seen in all cases. There was one procedural type I endoleak that resolved without reintervention at one month. There were no device-related endoleaks, but one type II endoleak was seen at one month. There were no deaths or neurological events. There were no site reported serious adverse events related to the device," he said.

Dake explained that the procedure to deploy the device included inserting the guidewires in aorta and branch vessel; introducing the aortic component over both guidewires into position within the arch; deploying aortic component and withdrawing catheter; advancing the introducer sheath and dilator and advancing and deploying branch component.

In order to be enrolled, patients had to have descending thoracic aortic aneurysms requiring placement of the proximal extent of the aortic stent graft in zone 2. The primary endpoints of the study were: successful access and deployment of the thoracic branched endograft and the primary patency of the side branch assessed by angiography when the procedure finishes. The secondary endpoints included a one-month core lab analysis, assessing the side branch primary patency and device-related endoleaks.

Arko told delegates that there was a clinical need for left subclavian artery preservation in association with encroaching thoracic artery aneurysm. He presented the current status of an early feasibility trial in the FDA's new innovation pathway testing the Valiant Mona LSA device.

Michael Dake

The key goals of the trial are to validate the procedure in humans; assess the safety and performance acutely and at 30 days and collect imaging data to augment the current understanding.

Arko told delegates that the Valiant Mona LSA Thoracic Stent Graft consisted of a flexible cuff "volcano" on the main body. The system is a two-graft system and the main graft system comes in diameters between 30 and 46mm and in the single length of 15cm. It is a two-wire system as well and the secondary wire can be snared and then the second branch is brought up and deployed. The branch graft itself is made of a nitinol helical wire and polyester fabric. It has a proximal flare. The branch graft is always 40mm in length and a 15F profile, femoral access system.

The early feasibility trial is a prospective, non-randomised, three-centre, premarket clinical study that has enrolled nine patients. The primary safety and effectiveness objectives were measured acutely and at 30 days. "The follow-up schedule will be at 0-30 days, six months, 12 months and annually through five years," Arko said.

The principal investigators are Eric E Roselli, Cleveland, USA, Frank R Arko, Charlotte, USA and Matt Thompson, London, UK.

Arko revealed that the current status of the early feasibility trial had seven patients enrolled as part of the US cohort and two enrolled as part of the cohort outside the US. One emergent case had been enrolled in the USA, outside of trial. Acute procedure results from all seven patients revealed 100% technical success and 100% patency in both main and branch stent graft. There were no type I or III endoleaks.

"All current devices need a healthy landing zone to seal. To achieve sufficient landing zone, the left subclavian artery may be sacrificed with resulting complications, such as 6% arm ischaemia, 4% spinal cord ischaemia, 2% vertebrobasilar ischaemia, 5% anterior circulation stroke and 6% death. Left subclavian artery preservation is recommended in the literature. 17–43% of patients undergoing TEVAR have planned coverage of the left subclavian artery to achieve an adequate proximal seal and the coverage of the left subclavian artery without revascularisation is the single most important predictor of post-TEVAR stroke," Arko said.

Still a lot to learn about abdominal compartment syndrome

A mini symposium on abdominal compartment syndrome held at the Charing Cross Symposium shed light on the condition. It became apparent that the syndrome is well defined, many of its triggering factors have been recognised, and its management is not limited to surgical decompression. Preventing intra-abdominal hypertension to developing into abdominal aortic compartment syndrome is the key to success, and this early treatment starts even before the operation, the delegates heard.

Martin Björck

Jan de Waele (Ghent, Belgium) stated that abdominal compartment syndrome has gone from being a syndrome that many vascular surgeons thought is "imaginary" to one that was now "being taken seriously." He added that, according to the definitions of the World Society of the Abdominal Compartment Syndrome (WASCS, www.wsacs.org), the syndrome was defined as sustained intra-abdominal pressure of 20mmHg with new organ dysfunction. "It can be a combination of haemodynamic problems, respiratory dysfunction, metabolic acidosis, and acute kidney dysfunction," de Waele commented. However, he reported that "organ dysfunction sets in if you just look for it" at the threshold for intra-abdominal hypertension (defined as a sustained pressure of 12mmHg or more). Therefore, he said it "made sense" to take steps to prevent both intra-abdominal hypertension and abdominal compartment syndrome. De Waele added: "We know the patients who are at risk, so we can really target intervention and we a have an indicator available—the intra-abdominal pressure."

Anders Wanhainen (Uppsala, Sweden) explained that the WASCS had identified that risk factors for intra-abdominal hypertension and abdominal compartment syndrome included diminished abdominal wall compliance, increased intra-abdominal contents, capillary leak/fluid

resuscitation, and increased intra-luminal contents. He noted that many of these risk factors were "relevant for vascular surgeons, particularly those managing patients with ruptured abdominal aortic aneurysms." For example, Wanhainen explained, ruptured aortic aneurysms are associated with major trauma, intra-abdominal fluid collection, acidosis, hypothermia, polytransfusion, and shock or hypotension. He added: "Repair of a ruptured abdominal aortic aneurysm is definitely a high-risk procedure for the development of abdominal compartment syndrome." According to Wanhainen, a study found that about 50% of patients undergoing open repair develop intra-abdominal hypertension and about 20% develop abdominal compartment syndrome. He added that these figures were, respectively, about 20% and 10% in patients undergoing endovascular aortic aneurysm repair (EVAR) but commented: "The observed lower risk after EVAR for a ruptured abdominal aortic aneurysm will probably change when more patients in shock are treated with EVAR."

Martin Björck (Uppsala, Sweden) also stated that prevention was important in the management of intra-abdominal hypertension/abdominal compartment syndrome. In the context of EVAR/open repair, he said that prevention "started at the operating table", or even before the operation He noted that this involved "a massive transfusion protocol and avoiding crystalloids," agreeing with de Waele that it was "crucial" to monitor intra-abdominal pressure in all patients after aortic aneurysm repair in the postoperative period.

Björck noted: "We prevent abdominal compartment syndrome with aggressive medical management [in patients with intra-abdominal hypertension] but sometimes abdominal decompression is necessary." He added, in terms of medical management, early pain relief could be "remarkably effective" and neuromuscular blockade, if the patient needs mechanical ventilation, was also very effective.

Björck reported that the recently updated 2013 WASCS guidelines were able to give strong recommendations for the management of abdominal compartment syndrome. He said that the guidelines recommend decompression laparotomy if abdominal compartment syndrome was present, protocolized effort should be made to obtain an early abdominal closure as "severe complications" can occur if open abdomen therapy is prolonged more than two weeks. Strategies using negative pressure wound therapy and avoiding lateralization of the bowel wall should be used, one such method that has shown excellent results in multiple studies is the combination of VAC and mesh-mediated fascial traction. Björck agreed with de Waele that although there are no evidence to support open abdomen treatment as a routine preventative treatment, it "made sense" not to close a tense abdomen [in patients undergoing open repair].

Critical care

De Waele also spoke about the management of intra-abdominal hypertension/abdominal compartment syndrome, focusing on critical care. He said that the introduction of medical management options to decrease intra-abdominal pressure had "significantly changed the management of patients with intra-abdominal hypertension" and expanded on the WASCS recommendations—"The WASCS medical management algorithm identified five targets for medical interventions such as nasogastric decompression, neuromuscular blocking agents and percutaneous drainage among others. It is estimated that medical management can avoid surgery in a large proportion of patients with impending abdominal compartment syndrome." However, de Waele said that surgical decompression remained an important element in the armamentarium and "may still be required" in some patients with therapy resistant abdominal compartment syndrome and significant organ derangement." Concluding, he said that the management of abdominal compartment syndrome had now become the management of intra-abdominal hypertension as monitoring intra-abdominal pressure was the "first and essential step" and prevention should be used where possible.

Charing Cross chairman Roger Greenhalgh told *Vascular News*: "If I were a young physician, looking for an area to elucidate, I would choose abdominal compartment syndrome."

Office-based PEVAR: "a natural progression"

In a single centre feasibility trial, six patients underwent office-based percutaneous endovascular aneurysm repair (PEVAR) with a "largely perfect" outcome. Principal investigator Stuart Harlin told *Vascular News* that office-based PEVAR is a "natural progression" as the in-hospital procedure is no longer financially sustainable.

The prospective, single centre, non-randomised trial study examined the initial experience of performing elective PEVAR in an office-based centre with same day discharge. The devices used for these procedures were the AFX endovascular AAA system (Endologix) and the Perclose ProGlide suture mediated closure system (Abbott Vascular).

The primary endpoint was 30-day treatment success. Secondary evaluations included all serious and non-serious adverse events, perioperative evaluations: anaesthesia time; fluoroscopy time; contrast volume used; time to haemostasis; procedure time; estimated blood loss; time to ambulation; time to normal diet; time to actual discharge; use of analgesic for groin pain, stent graft patency and integrity, quality of life survey.

Harlin, from Coastal Vascular Interventional Center, Pensacola, USA, explained that patients were carefully chosen based on their anatomy and health status. Six subjects between the ages of 52 and 87 undergoing elective PEVAR were enrolled. The aneurysms varied from 4.4cm and 5.8cm (all meeting inclusion criteria), 100% of patients were current smokers and had high cholesterol, 66.6% of patients were being treated for hypertension, 50% had coronary artery disease, 33.3% were diagnosed with diabetes.

All patients were treated with PEVAR and discharged the same day. A combination of PO Valium (10mg), IV Fentanyl (2.4mg) and IV Versed (130mcg) was used for sedation. Ultrasound was used to gain access into the common femoral arteries. All patients received 5000 IU Heparin IV. Bilateral ilio-inguinal blocks utilising Marcaine were administered.

"The average case time was 50 minutes and all the patients did perfectly. We got the patients up at four hours and they were discharged at six hours. We saw them the following day and then weekly for a month, and then did follow-up studies at one month. We had a largely perfect outcome—no one was admitted to the hospital, there were no infections and no anaesthesia complications," Harlin reported.

Stuart Harlin

Prior to discharge a femoral ultrasound was performed to evaluate access site integrity. During follow-up, access sites, pulse, pain tolerance and overall health were monitored. A CTA of the abdomen and pelvis, and femoral ultrasound was performed at 30 days. Two of the six patients reported painkiller use within 24 hours post operation, but none used narcotics thereafter. One patient experienced penile swelling at nine days, but this resolved without treatment.

In terms of the true difference between in-hospital and office-based PEVAR, Harlin explained that technically, the procedure is carried out the same way, but there is an OR team on standby in the building rather than in the room.

"As far as the conduct of the aneurysm repair, it is exactly the same way as they do it in the hospital. We use exactly the same imaging systems, catheters, guidewires. We do not have an OR team in the room. Our cath-lab team was in the room and the doctors were in the room, but other than that we try to make this procedure exactly the same as the hospital, just in a less acute setting," he said.

Harlin went on to say that the greatest concern throughout the trial as it relates to risk was how they would respond if one of the patients suffered a complication, for example, a cardiac event.

"So we had a transfer agreement with one of the hospitals already in place and with the ambulance service such that if there was a complication we had immediate access to get the patient to the hospital within 10 or 15 minutes. We had everything in place beforehand, but really our consideration was to minimise the risk of complication by choosing the patients very carefully," he stated.

Harlin said that there will be a separate publication on the cost-effectiveness of outpatient PEVAR, indicating that based on recent publications on in-hospital PEVAR, the former cuts the cost by 45%.

"The total cost for these cases was a little less than US$18,000, including grafts, our centre costs, balloons, bandages, antibiotics, pain killers, everything. That is out-the-door cost. If you compare it to in-hospital procedure, in all honesty, it is a little less than half," he reported.

Debate at SVS

In June, Harlin will be part of a debate at the Vascular Annual Meeting (5–7 June, Boston, USA) about whether office-based PEVAR is going to become the future of aortic intervention. He divulged that one of his primary arguments in favour of this is going to be the cost.

"I think this is a natural progression of the process. The novelty of same day discharge is no longer there, and it seems a natural progression to do it in an outpatient centre where it costs less money to do. The overheads in these centres are so much less that it makes a giant cost difference," he said.

Harlin added that the next step from the feasibility trial will be to a multicentre trial to demonstrate the safety of office-based PEVAR across several centres and then from that to define the specific patient population that will benefit. He said that those patients with challenging anatomy are not appropriate for an outpatient setting, at least not initially. Moreover, Harlin maintained that going forward, it will also be important to identify the doctors who can perform PEVAR safely in an office-based setting.

CX ilegx Collaboration Day hosts Endovascular Electronic Education and focuses on key approaches to save limbs

At the ilegx Collaboration Day, held during the Charing Cross Symposium (5–8 April 2014, London, UK), attendees learnt about the best management therapies for diabetic foot care and vascular reconstruction in critical limb ischaemia patients and for the second year running, the symposium broadcast edited live cases treating superficial femoral artery lesions to the Far East and North America in an event named Endovascular Electronic Education, sponsored by Abbott Vascular.

In the morning, three edited live cases were showcased to the Far East. The first case was performed by Andrej Schmidt in Leipzig, Germany, the second procedure was carried out by Peter Goverde in Antwerp, Belgium, and the third case was performed by Josef Tacke in Passau, Germany. The Abbott Supera stent system was used to treat occlusion and total occlusion of the superficial femoral artery and proximal popliteal artery.

Schmidt, Goverde and Tacke were present to answer questions from the audience at CX and those watching the live broadcast in the Far East.

Responding to questions about how a physician chooses a stent, Schmidt said: "In some cases it is clear—if it is a calcified lesion, for me it is clear that a drug-eluting balloon might not be so good, we know this from our data, and the Supera stent is the stent of choice." He added that more data are required to make the stent selection process more comprehensive.

In the afternoon, edited live cases were broadcast to North America.

EEE

Michael Edmonds

Early referral, fast track care and multidisciplinary work: key approach to save limbs

The ilegx initiative, launched in 2008, was created in response to the increasing number of lower limb amputations which are mostly due to type II diabetes. Michael Edmonds (London, UK) who is one of the founders of ilegx, introduced the "diabetic foot care" session, which was organised in conjunction with the King's College Hospital Open Access System, with a presentation which highlighted the importance of early diabetic foot referral and interdisciplinary work as an effective approach to reduce the number of lower limb amputations, flagship principles of the ilegx initiative. He said: "Up until recently, the diabetic ischaemic foot has defeated every health care system in the world. However, a strategy which combines early referral and interdisciplinary working has led to improvements in care." With this in mind, he commented, "ulcers can now be healed and amputations can be prevented."

Edmonds also referred to the importance of organising a "fast-track" service in a "one-stop" visit, comprising clinical assessment, same-day investigations and urgent management to treat infection and revascularise the foot, when dealing with cases of "diabetic foot attack." "This is best carried out in a diabetic foot clinic which can see the ischaemic patient in an open access system without delay and has rapid availability of debridement and intravenous antibiotics to treat infection and control the septic vasculitis." He also said that diabetic foot patients who experience repeated crises from the rapid onset of infection need a special form of such easily accessible care provided by the diabetic foot clinic. "Such integrated fast track care can rapidly restore the circulation, limit tissue necrosis, save the limb from amputation and provide complete recovery from the foot attack," he commented.

An interdisciplinary team including podiatrists, nurses, orthotists, microbiologists, interventional radiologists and surgeons—including vascular surgeons, orthopaedic surgeons and plastic surgeons—is the ideal team required in the management of diabetic foot, Edmonds noted.

He also mentioned that to complete an effective management of diabetic foot, follow-up and rehabilitation are required.

Interdisciplinary views on diabetic foot care

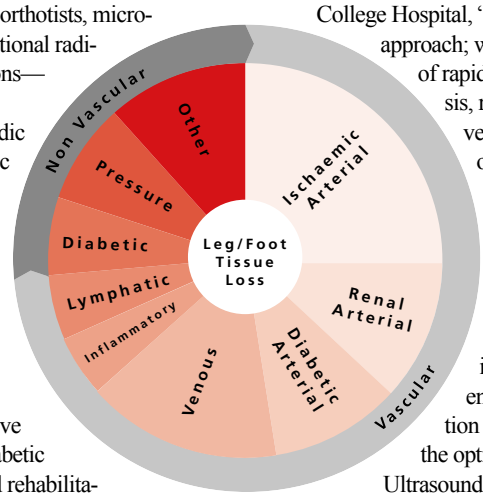
A vascular surgeon, an interventional radiologist and a podiatrist from King's College Hospital, London, UK, shared with CX delegates their best practices treating diabetic foot.

Vascular surgeon Hisham Rashid, said that "the incidence of type II diabetes mellitus is increasing across the world with an expected rise in 2030 to more than 12% in a large population of the world." This is a worrying figure taking into account that "a major amputation rate is significantly higher in diabetic patients," he noted.

Rashid told CX delegates that aggressive revascularisation with angioplasty, bypass or hybrid techniques is essential for limb salvage and reduction of major amputation rate. He mentioned that at King's College Hospital, 77% of cases are treated with angioplasty and 23% with distal bypass. He said that distal bypass surgery "plays a major role in revascularisation, especially in patients presenting with significant tissue loss and when angioplasty is not feasible." Hybrid techniques in "no-option" critical leg ischaemia have also proven very effective in preventing major amputation in this challenging group of patients, he commented.

At King's, Rashid noted, revascularisation using distal and ultra-distal bypass has a very good outcome with a one-year amputation rate of 3.4% and 30-days mortality rate of 1.5–1.7%. At one-year, "mortality is significantly influenced by end-stage renal failure and age rather than diabetes mellitus," he said.

Interventional radiologist Dean Huang, said that the concept of "foot attack" and "time is tissue" in diabetic patients means that treatment of an infected ulcer should be handled as an emergency with the management of a multidisciplinary team. At King's College Hospital, "we follow this approach; we work on the basis of rapid access to diagnosis, rapid access to intervention and follow-up of interventional and surgical procedures." From the interventional radiologist perspective, he said, "rapid access to imaging diagnostics enables the selection and planning of the optimal strategy."



Ultrasound, CTA and MRA have their place and angiography remains the gold standard, he commented. "Prompt definitive treatment with radiological intervention and/or surgical bypass to revascularisation for healing in conjunction with wound care and antibiotics is the key to achieve prevention of amputation," Huang noted. "The threshold of what can be treated with endovascular procedures is shifting as more sophisticated devices appear on the market."

Podiatrist Jennifer Tremlet, spoke about the different techniques used at King's College Hospital to heal diabetic foot wounds. "Diabetic foot patients are complex cases, they experience extensive tissue loss and infection. In order to achieve successful wound healing, they require intensive wound care and rigorous monitoring." She said that, depending on the complexity of the wound and the type of patient, they use different multi-modal techniques including debridement, larvae therapy, hydrosurgery therapy topical negative pressure therapy, split skin grafts and pressure relief.

Foot care and arterial reconstruction

At a session on foot care and arterial reconstruction, Christopher Attinger (Washington, USA) said that using the angiosome principle to guide revascularisation is a critical component for optimising wound healing. He explained that the angiosome concept divides anatomic regions into three-dimensional blocks of tissue fed by source arteries and creates a framework for understanding tissue perfusion, predicting wound healing, and planning surgical interventions. Therefore, "understanding the boundaries of an angiosome and the vascular connections between source arteries provides the basis for limb salvage to optimise revascularisation to ischaemic areas and promote wound healing."

Mauro Gargiulo (Bologna, Italy) spoke on the need to have multidisciplinary guidelines to support the treatment of critical limb ischaemia. He referred to a consensus document that has been recently published on the treatment of peripheral arterial disease in diabetes written by the Italian Societies of Diabetes (SID, AMD), Radiology (SIRM) and Vascular Endovascular Surgery (SICVE). The consensus, published in Nutrition, Metabolism & Cardiovascular Disease (Aiello A *et al*, 2014; 24: 355–369), higlights that "the prevalence of peripheral arterial disease is high in diabetic patients and, associated or not with peripheral neuropathy, can be found in 50% of cases of diabetic foot." Gargiulo said that the document summarises indications for revascularisation, revascularisation techniques and details on follow-up of revascularised patients, among other topics.

In the same session, Bijan Modarai spoke about effective cell therapies for revascularisation of critical limb ischaemia and Roberto Ferraresi discussed patient-centric revascularisation strategies.

At the end of the ilegx Collaboration Day a roundtable consensus on the role of drug-eluting balloons for the treatment of superficial femoral artery including data from the IN.PACT SFA, ILLUMINATE, Levant 2 and BIOLUX-PI studies was held.

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SOLUTIONS FOR VASCULAR DISEASE

Renal denervation comes to "a grinding halt" but studies will continue

The long-awaited results of the SYMPLICITY HTN-3 study show that the Symplicity renal denervation system (Medtronic) reduces blood pressure in patients with resistant hypertension to a similar extent as a sham procedure, with the difference between the two procedures not even approaching significance (p=0.26). However, Medtronic has said it still believes that renal denervation represents a "promising opportunity" to treat resistant hypertension.

When Medtronic released a press statement earlier this year that announced its sham-controlled SYMPLICITY HTN-3 study had failed to meet its primary efficacy endpoint, the overriding message in the interventional cardiology community was that the full results of the study were needed before any definitive conclusions about the future of renal denervation could be drawn. Now that the full results, published in *The New England Journal of Medicine* and presented at the American College of Cardiology annual meeting (ACC; 29–31 March, Washington DC, USA), have been released, there will be much speculation as to why the study failed to show any benefit of the intervention.

The SYMPLICITY HTN-3 trial was a randomised, sham-controlled study in which 535 patients who had an office systolic blood pressure of ≥160 mmHg despite being on a stable medication regimen of three or more antihypertensives were randomised to receive renal denervation with the Symplicity system (364) or a sham procedure (171). The primary efficacy endpoint was the change in office systolic blood pressure (from baseline to six months) in the renal denervation arm compared with the change (over the same time period) in the sham-procedure arm. Study presenter Deepak L Bhatt (Brigham and Women's Hospital Heart and Vascular Center, Harvard Medical School, Boston, USA) said that to show superiority of the system, there needed to be a superiority margin of 5mmHg in the renal denervation arm. He added that the secondary efficacy endpoint was "A comparison of mean 24-hour ambulatory systolic blood pressure change from baseline to six months in the renal denervation arm compared with change from baseline to six months in the control arm [with a superiority margin of 2mmHg]."

At the six-month follow-up point, there was a significant reduction in blood pressure in both groups. However, there was no significant difference in blood pressure reduction between the renal denervation group and the sham procedure group: -14.13±23.93mmHg vs. -11.74±25.94mmHg, respectively (a difference of -2.39mmHg; p=0.26). Bhatt reported that no significant differences were observed in any of the subgroups (eg. diabetes), and added that the secondary efficacy endpoint (reduction in ambulatory blood pressure) was also not met: -6.75±15.11mmHg for renal denervation compared with -4.79±17.25mmHg for the sham procedure (a difference of -1.96mmHg; p=0.98). He noted that despite not meeting its primary or secondary efficacy endpoints, SYMPLICITY HTN-3 did meet its primary safety endpoint as the Symplicity system did not significantly increase the risk of major adverse events compared with the sham procedure (1.4% vs. 0.6%, respectively; p=0.67). "In a prospective, multicentre, randomised, blinded, sham controlled trial of patients with uncontrolled resistant hypertension,

Deepak L Bhatt

percutaneous renal denervation was safe but not associated with significant additional reductions in office or ambulatory blood pressure," Bhatt summarised.

Reflecting as to why the study failed to show a benefit of renal denervation whereas previous studies (eg. SYMPLICITY HTN-1 and SYMPLICITY HTN-2) have, Bhatt commented that the limitations of the study may have affected the results. However, he added that there was evidence to suggest that the results of the study would have been the same even without these limitations. For example although the six-month follow-up point may have been "too short" to show a significant difference between the procedures, he stated, "prior studies had found benefit by six months." Also, while the SYMPLICITY investigators did not assess drug adherence by measuring blood or urine levels, they did measure adherence at six months through patient diaries and did not observe a difference between the groups.

However, although the study failed to show a benefit of the renal denervation system, Bhatt did not suggest that SYMPLICITY HTN-3 signalled the end of renal denervation as a treatment option for resistant hypertension. He concluded: "Further study in rigorously designed clinical trials will be necessary to confirm previously reported benefits of renal denervation in patients with resistant hypertension or to validate alternate methods of renal denervation." He added that the results of SYMPLICITY HTN-3 "underscore the importance of blinding and sham controls in evaluations of new devices."

In a commentary in *The New England Journal of Medicine*, Franz H Messerli and Sripal Bangalore (Division of Cardiology, Mount Sinai Roosevelt Hospital, Icahn School of Medicine and the Leon H Charney Division of Cardiology, New York University School of Medicine, respectively, New York, USA) called the difference in blood pressure reduction between the Symplicity arm and the sham-procedure arm "paltry" and said that the SYMPLICITY HTN-3 study brings "the renal denervation train to a grinding halt." However, they write that the wide variability in response to renal denervation observed in studies "begs the question of whether this procedure could be more efficacious in selected patients with increased sympathetic drive only, such as those with heart failure" and conclude "the time has come to turn the page on renal denervation for hypertension but by all means, let's not close the book."

Medtronic has indicated, for the time being, it has no plans to "close the book" on renal denervation. Following the recommendations of an independent panel, the company has announced it will discontinue the already suspended SYMPLICITY HTN-4 study (which was assessing renal denervation in patients with moderate resistant hypertension) but says it will continue to enrol patients in the Global SYMPLICITY registry. Nina Goodheart, vice president, general manager, Renal Denervation, says: "Based on the unique nature of these findings and support from the independent panel that additional research be considered to better understand the effects of the Symplicity technology for renal denervation, we remain convinced that resistant hypertension is a large unmet medical need and renal denervation remains a promising opportunity."

Gore recognises 2014 Pioneers in Performance for Europe

Gore has honoured four European physicians as Pioneers in Performance. The biennial award acknowledges exceptional work in the field of vascular and endovascular therapy.

The 2014 nominees were selected by past award recipients in four categories. Through popular vote on pioneersinperformance.com, the broader medical community chose to award the following honourees at a special celebration during the Charing Cross Symposium held in London, 5–8 April 2014:

- Commitment to Ongoing Learning: **Krassi Ivancev**, professor and head of the Complex Endovascular Aneurysm Treatment Team at The Royal Free Hospital, London, UK
- Dedication to Sharing Knowledge with Peers and Patients: **Dierk Vorwerk**, chairman of the Department of Diagnostic and Interventional Radiology at Ingolstadt Hospital, Ingolstadt, Germany

Fabrizio Fanelli, Krassi Ivancev, Roger Greenhalgh, Marty Sylvain, Dierk Vorwerk and Jim A Reekers

- Dedication to Creating Consensus within the Medical Community: **Fabrizio Fanelli,** professor of Interventional Radiology at the University of Rome La Sapienza, Rome, Italy
- Dedication to Analysis of Clinical Outcomes: **Jim A Reekers**, professor of Interventional Radiology at the Academic Medical Center, Amsterdam, The Netherlands

Roger Greenhalgh, chairman of the Charing Cross Symposium and a past recipient of the award, commented: "Pioneers in Performance celebrates the incredible achievements made by proven leaders in our field by honouring their dedication to excellence through innovation, critical thinking, education, research, and collaboration. This year's honourees exemplify what it means to be a true pioneer in the pursuit to advance open and endovascular surgery and improve patient outcomes."

"Since the Pioneers in Performance programme began, physicians from all over the world have been given the opportunity to honour the extraordinary achievements of their peers and this year is no different," said David Abeyta, leader of the Gore Medical Products Division. "We congratulate this latest group of European-based honourees and thank them, and their fellow nominees, for their unrelenting dedication to advancing vascular and endovascular therapy for their patients and their peers."

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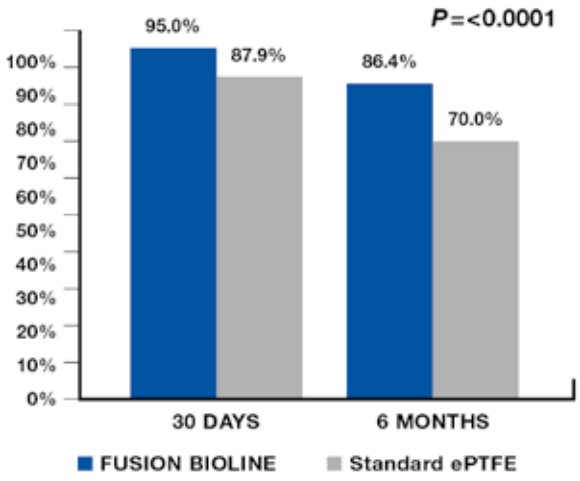

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Vascular trainees recognised for best presentations

Three vascular trainees were rewarded for their work during a presentation at the end of the European Vascular Surgeons in Training Presentations session, which was held at the Charing Cross Symposium on Tuesday 8 April 2014.

At the event, trainees presented on varying topics from, among many others, aneurysm rupture, popliteal aneurysm exclusion, vascular access and management of infections after EVAR. In first place was David Bosanquet, Swansea, UK, for the paper, "Predicting outcomes in native arteriovenous forearm fistulae: the CAVEA2T2 scoring system". Awarded second place for the paper "Autologous aortic venous reconstruction: a single centre experience with long-term follow-up" was Willem Thijsse, Alkmaar, The Netherlands. Finally, in third place was Mario Marques Vieira, Porto, Portugal, for the paper "Coronary-subclavian steal syndrome".

Hubert Stepak, David Bosanquet, Willem Thijsse, Vincent Jongkind and Igor Banzic

UK All Party Parliamentary Group condemns figures on regional variation in amputation rates

Thousands of patients may be facing unnecessary leg amputations, owing to variations in practice around the UK. A new report from the All Party Parliamentary Group on Vascular Disease draws on new data from Freedom of Information requests to NHS Trusts and Clinical Commissioning Groups to draw attention to the variation around the country in amputation rates and implementation of the best clinical practice.

Neil Carmichael, chair of the Group, said: "Too many patients are not getting the treatment they need to avoid losing their legs. The figures for parts of the South West of England are particularly alarming, and this needs to be tackled. The All Party Parliamentary Group on Vascular Disease, working with the country's top experts in this field, recommends that the Department of Health make reducing lower limb-loss a major priority. This is especially important given the country's ageing population." He added: "The unacceptably high level of lower limb amputations among people with diabetes in certain areas is a real cause for alarm. There clearly is a serious problem if some regions of England have much higher amputation rates than others."

Amputations are dependent on where you live, which is dependent on the service provision policies of local health authorities. There is no nationally consistent policy on how to treat patients with peripheral arterial disease. Amputation is twice as likely for patients in the South West as it is in London. Even patients in the second best performing region, the North West, have a 31% greater risk of amputation.

In 2012–2013, there were almost 12,000 lower limb amputations in England. The vast bulk of these lost limbs were related to peripheral arterial disease and diabetic foot disease.

A major driver of high amputation rates is the lack of a specific patient pathway for dealing with peripheral arterial disease patients. The data from the Freedom of Information request showed that from 2009 to 2012, Clinical Commissioning Group areas without a patient pathway had 11% more amputations on average than those with a patient pathway.

A further driver of high amputation rates is the lack of multidisciplinary teams. In spite of strong evidence that such teams are essential to ensure high standards of care, 30% of trusts handling vascular and diabetes patients lacked multidisciplinary teams for diabetes. Twenty eight per cent of Trusts lacked multidisciplinary teams for peripheral arterial disease.

Studies have shown that rapid treatment within 24 hours can reduce the risk of critical limb ischaemia; however, there are no national guidelines for the speed of referral for a patient suspected of critical limb ischaemia.

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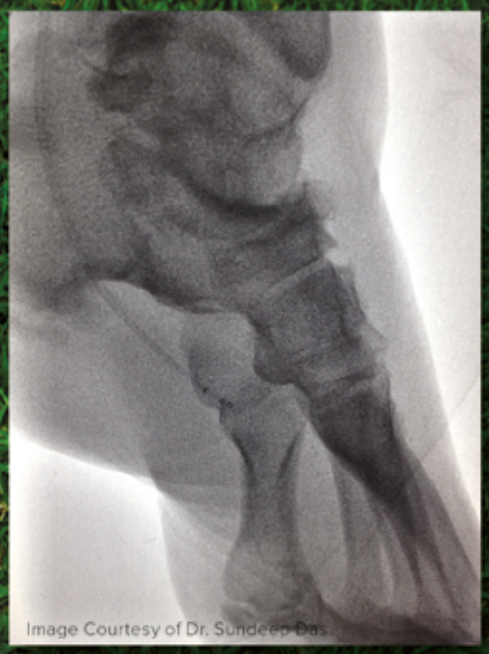

Image Courtesy of Dr. Sundeep Das

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Profile Cliff Shearman

Cliff Shearman is professor of Vascular Surgery, University of Southampton, and a vascular surgeon in the Department of Vascular Surgery, University Hospital Southampton Foundation Trust. A former president of the Vascular Society of Great Britain and Ireland, Shearman was involved in the process that culminated with the approval of vascular surgery as a new speciality in the UK. He tells *Vascular News* about his mentors, proudest moments, memorable cases and interests outside medicine – including running the London Marathon this year.

When did you decide you wanted a career in medicine? Why vascular surgery?

I was a typical school student who was interested in science and biology and did not have much idea of how to make this a career. No one in my family had ever done medicine and I must admit I had not got a clue at 17 years of age what it entailed. However, I had a relative who was a scientist and worked at the Medical Research Council and he got me a holiday job working in a research laboratory. I found it really quite bizarre that some of the incredibly bright people I worked with had spent their whole life studying a single molecule and everything revolved around this. I realised this was not for me. However, during the lunch breaks I used to meet some of the medical students from the nearby medical school and I soon realised that clinical medicine was what I really wanted to do. I started medical school just after the first heart transplants were being undertaken and cardiovascular surgery seemed to me the most important thing in medicine and I initially wanted to do cardiac surgery. However, by chance I did a vascular surgery job just before I was due to start a cardiac training scheme and was hooked immediately.

Who has inspired you in your career and what advice of theirs do you remember today?

There have been a number of people and organisations that had a profound effect on me and my development. I still almost on a daily basis remember some of them and use the skills they taught me.

Having trained in London I left to work in the Birmingham Accident Hospital, which at that time was the only dedicated trauma hospital in the country. I worked for Peter London who had been instrumental in developing this unit and making the premier place to train in trauma surgery. He taught me the importance of attention to detail and how often it is the small things that make a difference to a patient's outcome. He also impressed me on the value of letting colleagues know when you were grateful to them. Peter London was very formal and always used surnames to address the team. However, after a very busy weekend in which we had all worked pretty much flat out, he caught me eating breakfast on the ward which was not allowed. I thought I was in for a dressing down but he came and joined me and told me how impressed he was with my performance. I cannot tell how good that made me feel for months afterwards.

The person who had the biggest impact on my vascular career was Malcolm Simms, a very gifted vascular surgeon in Birmingham. It was in fact working for him which persuaded me that vascular surgery was what I really wanted to do. It was not just because he was good at his job, but he was probably the most enthusiastic person I had ever met in medicine and who enjoyed every minute of the job. I also learnt from him not to give up when things got tough and I hope that is something I have stuck with to this day. The time to consider all the challenges is before the beginning of an operation. Once you have started, the role of the surgeon is to overcome any unexpected obstacles to get the best outcome for the patient. He very much had the same attitude to long-distance running which he got me involved with and I still think there are a lot of similarities to surgery.

After four years as a consultant in Birmingham I had a difficult career decision to make and for a range of reasons I moved to Southampton. At that time I think I was a fairly typical surgeon interested only in my own service and speciality area, but the chief executive of my new hospital arranged for me to be seconded to the King's Fund, a management college in London. I spent over a year intermittently working there and to this day the skills I learnt in managing people and myself I think have kept me sane and still enjoying the job. Probably most importantly I learnt that if you really want to improve a service you do not do it working on your own and moaning about things.

What have your proudest moments been?

Undoubtedly, becoming president of the Vascular Society of Great Britain and Ireland in 2010. As a vascular surgeon I had been a member of the vascular society all my career and it had had a major influence on most aspects of my professional life. For me it was a particular pleasure to be president in 2010 as a whole team of presidents and council members had been working hard to get vascular surgery recognised as a new speciality in the UK and there was a real energy in the society to achieve this at that time.

Vascular surgery as an independent specialty was approved by the Parliament in March 2012. How have the vascular surgery curriculum and its implementation developed since then?

Soon after the new speciality was approved in 2012 the training curriculum, which includes endovascular training, was approved by our General Medical Council. We recruited our first intake of trainees in 2013. We were really encouraged that 273 trainees competed for the 20 national training posts indicating that vascular surgery is still a popular career choice. We are just about to recruit our next year's intake and again have had similar numbers of applications so the future is looking good.

How has vascular surgery evolved since you began your career?

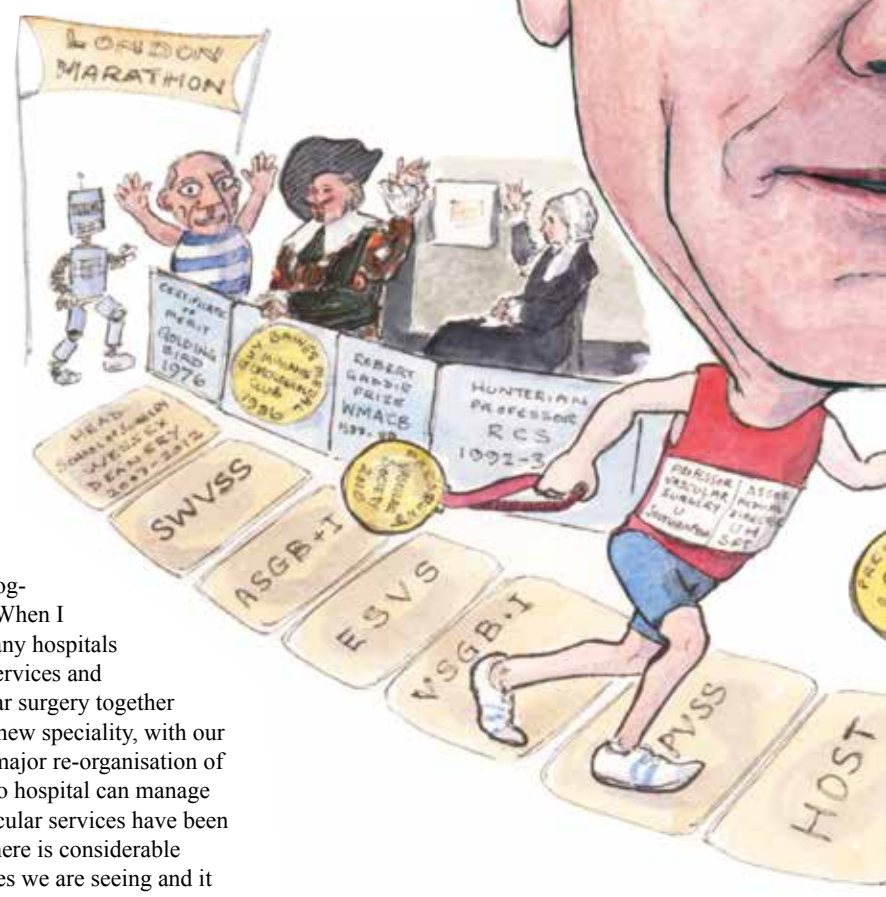
To me the biggest change has been to see vascular surgery recognised as a vital clinical service. When I first started my career I think many hospitals reluctantly supported vascular services and many surgeons did some vascular surgery together with general surgery. Now, as a new speciality, with our own training programme and a major re-organisation of vascular services it seems that no hospital can manage without a vascular surgeon! Vascular services have been recognised as a major service, there is considerable interest in the improved outcomes we are seeing and it is top of the agenda in most hospitals.

What have your most memorable clinical cases been?

Obviously when a complex case goes well, as a surgeon you get a real buzz. However, the cases I remember most and have the most impact on me are when things have not worked according to plan and over the weeks and months afterwards you get to know the patient and their family well. Trying to repair a badly damaged iliac artery in a three-month old was very humbling and the child had to return to theatre three times. At one stage I had to warn the parents their child may lose its leg. To see the parents having to deal with this, but not being able to get the bypass to work at first was dreadful. Surprisingly over the years I still see the child who has done well and the parents remain friends!

How do you see the endovascular field developing in the future?

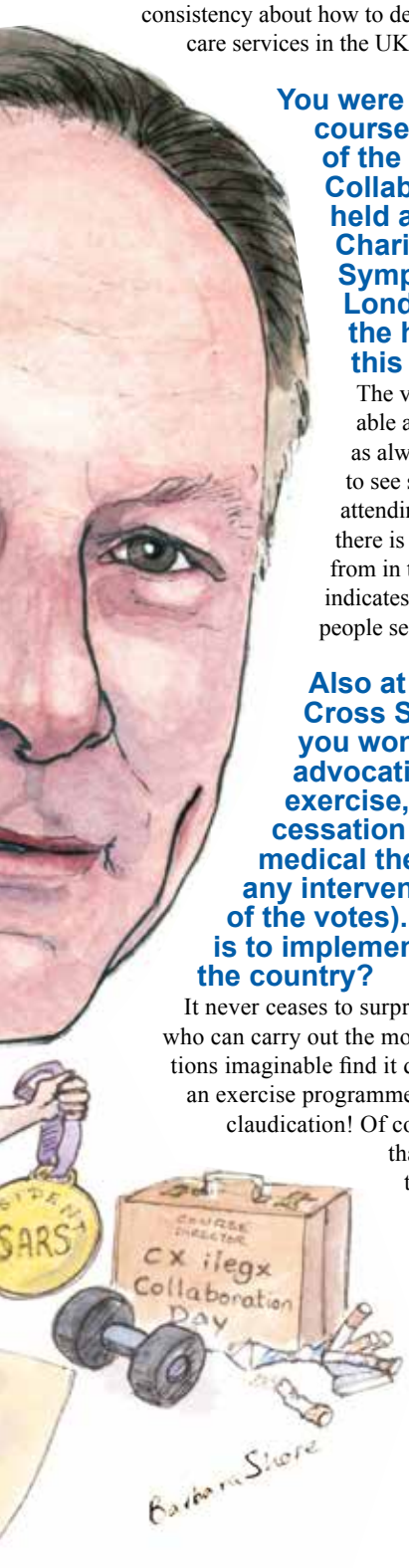
Endovascular interventions have made a major impact on the treatment of vascular disease. However, to me they are still a fairly



crude solution to the treatment of vascular disease and I cannot believe that in 10 years we will be delivering endovascular treatments in the same way as we do now. In the short term, I see the use of computer technology increasing. Computer models can already be used to predict individual patient outcomes. Robotic technology is also evolving, which can achieve many parts of the intervention without many of the human limitations. In the longer term, better understanding of the biology of vascular disease surely must allow more directed medical therapies to be developed.

Diabetes-related lower limb amputation rates are still high in the UK. How does your team in Southampton address peripheral arterial disease and diabetes in order to prevent amputations?

The pathway to reducing amputations is awareness of the problem and prevention by early intervention. Frustratingly, this does not need lots of investment or more vascular surgeons; it simply needs better team working across the community and hospital care. We showed many years ago that is simple to do this; it will reduce amputations dramatically and also save the service money. Despite this there is still considerable lack of consistency about how to design diabetes foot care services in the UK.



You were one of the course directors of the CX ilegx Collaboration Day held at the recent Charing Cross Symposium in London. What were the highlights of this year's course?

The venue was unbelievable and worked well but as always I was encouraged to see such a large audience attending the session. When there is so much to choose from in the programme it indicates to me how important people see this area.

Also at the Charing Cross Symposium, you won a debate advocating supervised exercise, smoking cessation and best medical therapy before any intervention (with 71% of the votes). How feasible is to implement this across the country?

It never ceases to surprise me that surgeons who can carry out the most complex operations imaginable find it difficult to introduce an exercise programme for people with claudication! Of course the reality is that many are not particularly interested. Exercise is highly cost-effective and for many patients it will allow them to avoid the need for intervention, but it does need to be enthusiastically promoted. Even for the sceptical vascular surgeon, a well-run exercise programme will mean that patients who get referred to them from the programme will genuinely need intervention.

What is your opinion about the publication of individual results from vascular surgeons (surgeon level reporting) in the UK?

It is now inevitable the surgeon specific outcomes will be published annually in the UK. I think it has been difficult for vascular surgery, who after cardiac surgery, have led the way and there have been some painful lessons learnt. However, now this becoming routine for all specialities I think it will be easier.

I do have concerns, however, that it will focus vascular surgeons on undertaking index operations that are reported rather than the provision of the overall service. The most onerous and busy part of my job is the emergency week and yet during that time I may do no elective index operations. In a specialty such as vascular surgery where there are enormous range of activities that vascular surgeons contribute to the service I think we will have to be very careful how they are recognised when looking at surgeon performance.

You have been involved with the training of young vascular surgeons. What skills does the vascular surgeon of the 21st century need to develop?

Enthusiasm and the ability to adopt new ideas. Much of what the next generation of vascular surgeons is taught as trainees will probably be obsolete within years. However, one of the joys of surgery is learning new technologies and introducing them into practice to benefit patients.

What is the most interesting paper you have come across recently?

Surprisingly it was not a paper on vascular surgery but one on how we adopt new technologies into surgery. Generally, compared with many other professions we are very slow at doing this and for things like computer modelling on the effects of intervention we are positively still in the Stone Age.

Outside of medicine, what are your interests?

Although a late starter I have always enjoyed travelling and experiencing new cultures and I have had a lot of opportunities to do that. I particularly like to understand the influence that art has had on society, and although I have no expertise in this area, being married to an art historian I am learning! I still run and find it helps me relax and think. Having not done a marathon for 10 years I ran the London Marathon this year. The painful lesson I learnt is that as you get older preparation counts for everything and with little training it took me over an hour longer than 10 years ago. Anyway, I will try again next to regain my former glory!

Fact File

Present posts

1999–present	Professor of Vascular Surgery University of Southampton, Southampton, UK
1999–present	Department of Vascular Surgery, University Hospital Southampton Foundation Trust
2008–present	Associate medical director, University Hospital Southampton Foundation Trust

Qualifications

1976	BSc (1st class honours), Intercalculated Medical Sciences, London, UK
1979	MB BS, London
1983	FRCS, England
1989	Master of Surgery, London

Medical education

1973–1979	Guy's Hospital Medical School, University of London
1980–1990	Postgraduate Education, Birmingham, UK

Posts held

Aug 1979–Nov 1979	House surgeon, General & Vascular Surgery, Guy's Hospital, London
Nov 1979–Jan 1980	House surgeon, Cardiothoracic Unit, Guy's Hospital, London
Feb 1980–Aug 1980	House physician, Lewisham Hospital, London
Sep 1980–Sep 1981	Senior house officer, Birmingham Accident Hospital
Feb 1982–Jun 1982	Senior house officer, Regional Neurosurgical Unit, Derbyshire Royal Infirmary
Jun 1982–Dec 1982	Registrar, Orthopaedics & Trauma, Dudley Road Hospital, Birmingham
Dec 1982–Jun 1983	Registrar, General Surgery, Dudley Road Hospital, Birmingham
June 1983–Dec 1983	Registrar, Paediatric Surgery, General, Orthopaedic & Neurosurgery, The Children's Hospital, Birmingham
Dec 1983–Jun 1984	Registrar, General Surgery, The General Hospital, Birmingham
July 1984–Mar 1986	Registrar, General Surgery & Urology, Selly Oak Hospital, Birmingham
Mar 1986–Jun 1988	Research fellow, Dept of Vascular Surgery, Selly Oak Hospital, Birmingham
Jul 1988–Oct 1988	Registrar, General Surgery, East Birmingham Hospital
Oct 1988–Oct 1990	Lecturer/honorary senior registrar, Department of Surgery, University of Birmingham
Oct 1990–Apr 1994	Senior lecturer/honorary consultant surgeon, Department of Surgery, Queen Elizabeth Hospital, University of Birmingham
May 1994–Sep 1999	Consultant vascular surgeon/honorary senior lecturer, Southampton University Hospitals Trust

CX Innovation Showcase highlights branched graft developments

Attendees at the CX Innovation Showcase learnt about the latest branched devices for endovascular aneurysm repair. New technologies for the vascular and endovascular treatment of lower limb, venous and carotid disease and arteriovenous access were also discussed. Stephen Greenhalgh (London, UK) and Andrew Holden (Auckland, New Zealand) were the chairmen of the session.

Greenhalgh told CX Daily News that the objective of this year's session was "to get an idea of the pipeline of the major companies to tackle branched endovascular aneurysm repair." Among the branched devices featured at the CX Innovation Showcase, Michel Makaroun, Pittsburg, USA, presented on the investigational TAG thoracic branched endograft from Gore. He said that the design of this off-the-shelf device started "nearly a decade ago". The device has been built upon existing aortic and peripheral platforms and can be adapted to many anatomies. It is easy to use, requiring only femoral access and minimal manipulations, and is safe with minimal risk of branch coverage, he noted. The device has an aortic component which incorporates an internal portal allowing seal and fixation of the side branch component. The device diameters are between 21 and 53mm and the aortic treatment ranges between 16 and 48mm. "We have very early clinical experience with the device and it has been positive so far," he concluded.

Zenith T-Branch and P-Branch endovascular grafts

Timothy Resch, Malmo, Sweden, spoke about Cook Medical's Zenith T Branch and P Branch endovascular grafts, which are off-the-shelf systems for complex aortic repair. These devices, Resch noted, are aimed to "eliminate complex planning as well as manufacturing delays in the treatment of aortic aneurysms".

The Zenith T Branch, designed to treat thoracoabdominal aortic aneurysms, has been CE-marked since 2012. Resch explained that the system consists of two main components that are compatible with the existing Zenith Thoracic Endovascular Aortic Repair (TEVAR) and iliac limbs components for proximal and distal extension depending on the aneurysm extent. The first component is a standard multi-branched device aimed at preserving flow into the main visceral side branches of the aorta. The second component is a "unibody" bifurcated device that comes in five different total lengths to match the individual anatomy. "Planning is simplified by using a predesigned planning sheet where the extent of the aneurysm as well as position of the target vessel ostia are marked," he noted.

Resch highlighted that clinical and anatomical studies have determined that the applicability of the device in the treatment of thoracoabdominal aortic aneurysm ranges from 70 to 80% of the cases and multicentre studies are ongoing to evaluate further the applicability and efficacy of the device.

Resch went on to present the Zenith P Branch endovascular graft. He said that this device is designed to treat juxtarenal and suprarenal aneurysms as well as short neck infrarenal aneurysms which are not suitable for standard infrarenal EVAR. "As with the T Branch system, the P branch has two main components and is compatible distally with standard Zenith iliac limb extensions," he said. In contrast to the T Branch, the P Branch consists of a main body including two fenestrations for the renal artery and one for the superior mesenteric artery as well as a scallop fenestration for the coeliac trunk. Planning is done in a standardised fashion using a planning sheet and a template outlining the device.

Resch told delegates that anatomical studies in patients with juxtarenal abdominal aortic aneurysm have estimated the applicability of the P Branch to 50–70% but clinical data are still lacking. The device is not commercially available and international, multicentre feasibility studies are ongoing.

Relay branched endograft

In a subsequent presentation, Toru Kuratani, Osaka, Japan, spoke about early and midterm results with the Relay branched endograft from Bolton Medical. He told delegates that he has been using the device, which is comprised of a flexible main body and two internal tunnels inside the main body, since 2013.

Early results in 12 patients treated with the Relay endograft have shown positive outcomes with 100% procedural success rate, no endoleaks, stroke or major complications, Karatani noted. At six months and 12 months, there was a 100% survival rate and 100% freedom from aortic events. He said that endovascular repair with this device "may become a wonderful option for high risk patients."

Jotec

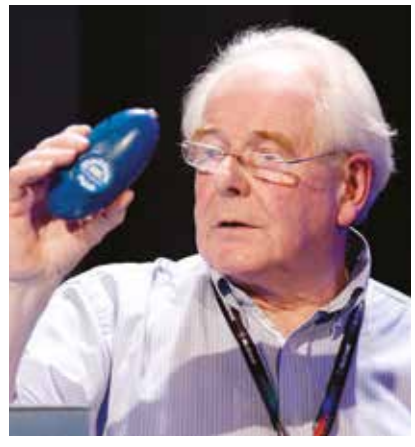
Martin Funovics (Vienna, Austria) presented a new branched endograft from Jotec. He told delegates: "If off-the-shelf technology fails, this is where the new technology from Jotec might jump in." The device is adaptable to variable design choices and the branches are flexible with easy cannulation, he noted. He reported that the initial results were also promising.

Nellix

The Nellix sealing system was featured at the Innovation showcase with presentations from Andrew Holden, Auckland, New Zealand, and Bob Mitchell, Hertogenbosch, The Netherlands. Mitchell told delegates that Nellix is a "game changer" in the treatment of abdominal aortic aneurysms. He said: "Nellix is not simply a next generation EVAR device, but it is rather a completely different approach to abdominal aortic aneurysm therapy. Nellix stands alone as the one and only alternative to EVAR." This is a breakthrough concept designed to dramatically reduce known EVAR complications such as endoleaks, migration and reinterventions, he added.

Michel Makaroun

Timothy Resch


David King

Michi

As a highlight in the latest carotid innovations, Sumaira Macdonald, Sunnyvale, USA, spoke on the Michi system (Silk Road Medical), a cervical access approach that is used to reduce the risk of microemboli in carotid stenting. Macdonald told the audience that early results with the device "are encouraging" and "may represent a paradigm shift in the management of carotid artery disease."

In the lower limb session, Michael Orlowski presented data for the Legflow Paclitaxel-Eluting Peripheral Balloon Dilatation catheter from Cardionovum.

David Deaton, Washington, USA, spoke on the Rox device for endovascular arteriovenous fistula; and Steve Elias, Englewood, USA, presented data on Clarivein, an endovenous ablation system used in the treatment of varicose veins.

Concluding the session, Greenhalgh told CX Daily News that there is a clear call from the audience for more evidence and more data from the technologies showcased. However, he added: "It is wonderful to see the rich pipeline of new devices that are coming."

Physicians share new product ideas at "Speed Dating" event

For the first time at the Charing Cross Symposium, physicians shared their product ideas with experienced physician inventors, engineers and marketing experts in an event called "Speed Dating". The event was held at the Innovation Showcase yesterday. Physician inventor David King (London, UK) won the "Dragons' Den CX Innovation Showcase prize".

Jean Bismuth, Elika Kashef and Stephen Greenhalgh, chairs of the session, designed the event to provide a platform for physicians who are seeking advice from experts on how to put their business and product ideas onto market.

Bismuth explained the rationale for the event: "Many young physicians and even senior physicians—as they gain experience through the years—have a desire to design their own medical tools and they start thinking and developing the idea. Unfortunately, sometimes they cannot get their innovations onto the market because they do not have the access to the experts to take the idea to the next level. With this "speed dating" event, we want to collaborate to bridge that gap."

At the event, physicians had the opportunity to speak first to a group of physicians who have experience developing devices, then to engineers and finally to marketing experts. "Protect your idea" was the main advice that experts gave to the participants.

After the "Speed Dating" event, the Dragons' Den CX Innovation session took place and awarded David King with £1,000 for his innovative idea. King designed a Doppler device called "Blue Dop" that works via a tablet device. He said that it uses a special algorithm that can measure blood pressure without the need to use a cuff or needles. He noted that the device is unique in the market and can be used in renal dialysis, arterial disease and sports medicine.

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Innovating for life.

Johannes Lammer and Peter Taylor retire

Two internationally renowned physicians and influencers of opinion, interventional radiologist Johannes Lammer and vascular surgeon Peter Taylor, are retiring from active practice. Both Taylor and Lammer retired in early April.

Johannes Lammer

Peter Taylor

Lammer, who originally wanted to be a filmmaker turned to interventional radiology almost by happenstance. In 2005, he told *Interventional News*: "The decision to go into medical school came about because in the summer I finished high school, the Austrian Government decided that those who were going to medical school did not have to join the army. I thought medical school was therefore a good option."

Since 1992, Johannes Lammer has been head of the department of Angiography, now Cardiovascular and Interventional Radiology in Vienna University Hospital, Vienna, Austria, and has been actively committed to furthering the cause of interventional radiology. A long-standing, active and highly valued member of the Cardiovascular and Interventional Radiological Society of Europe, he has served as its treasurer, secretary and president. Lammer has strongly advocated the concept of evidence-based medicine with more than 300 peer-reviewed publications in journals such as Radiology, Circulation, The Lancet, New England Journal of Medicine, CVIR and JVIR. He also serves on the editorial boards of several leading journals in the field.

His research interests include CT and MR angiography of coronary and peripheral arteries, interventional radiology treatment of peripheral vascular and aortic diseases, as well as hepatocellular carcinoma and liver metastases.

Lammer has received a number of awards and honours throughout his career, including honorary membership of the Austrian Society of Radiology, the Austrian Society of Interventional Radiology, the Hungarian Society of Interventional Radiology and the Turkish Society of Radiology. He has also received Honorary Fellowship of the British Society of Interventional Radiology and the Gold Medal of the Cardiovascular and Interventional Radiological Society of Europe.

Taylor, consultant vascular and endovascular surgeon at Guy's and St Thomas' NHS Foundation Trust, London, UK, was all set for a career in music alongside his three brothers before he decided to become a doctor. "Both my parents were musicians and they sent their first three sons to Durham Cathedral Choir School where we were choristers," he said.

Taylor was taught by Ronald Smith, a great pianist who specialised in works by Alkan. "My father encouraged us all to play a stringed instrument and I played the violin in various orchestras. I gained a choral exhibition to Emmanuel College and sang regularly in the choir," he stated when profiled in 2010.

His main interests lie in carotid and aortic intervention, particularly the endovascular treatment of aortic dissection. He has taken part in major randomised trials such as the UK Small Aneurysm Trial, the EVAR trials and the Asymptomatic Carotid Surgery Trial and recent research includes the investigation of patients with aortic dissection using functional magnetic resonance imaging.

Taylor was the 2008–9 president of the Vascular Society of Great Britain and Ireland and is the author of nearly a 100 peer reviewed papers published in a variety of journals. He is the convenor of Thoracic Masterclass held annually at Guy's Hospital along with John Reidy, consultant interventional radiologist at Guy's. Taylor refers to his successful collaboration with Reidy as the "the greatest influence. Together we navigated our way through the endovascular revolution and in particular found a unique niche in thoracic aortic endovascular work," he said.

Taylor was named a distinguished fellow of the Cardiovascular and Interventional Radiological Society of Europe in 2013 and a fellow of the British Society of Interventional Radiologists in 2010. He is co-chairman of the Charing Cross International Symposium.

Stent grafts more effective than angioplasty for failing dialysis access grafts at two years

The final, two-year data from the post market randomised controlled RENOVA trial, which set out to evaluate the longer-term safety and effectiveness of angioplasty and stent graft (Flair, Bard) treatment vs. angioplasty alone for treatment of arteriovenous graft venous anastomotic stenoses showed that stent grafts proved as safe as angioplasty, and more effective.

Ziv Haskal, Radiology and Medical Imaging, University of Virginia, Charlottesville, USA, presented the results at the Society of Interventional Radiology's (SIR's) 39th Annual Scientific Meeting (22–27 March 2014, San Diego, USA). The study was judged as the best clinical abstract of the year by the SIR.

"The Flair stent grafts provided a two-fold sustained advantage over balloon angioplasty in treatment area and overall access patency. There were fewer repeat interventions needed was less and the time to subsequent intervention was longer in the stent graft patients," Haskal said.

RENOVA, a 28-site, prospective, controlled US study enrolled 270 patients with malfunctioning upper extremity arteriovenous grafts with graft-vein anastomotic stenoses of ≥50%. One hundred and thirty two patients received balloon angioplasty and 138 received stent-grafts. Two-year outcome measures included: treatment area primary patency, overall access circuit primary patency and index of patency function.

Results

The investigators had complete data for 191 patients (97 stent graft patients and 94 balloon angioplasty patients). Five patients were lost to follow-up or withdrew; 74 patients died during the study (36 in the angioplasty group and 38 in the stent graft group). At 12 months, treatment area primary patency and access circuit primary patency were significantly better in the group that received stent grafts than the group that received angioplasty alone ($p<0.007$).

The results obtained with stent grafts remained significantly better at 24 months: treatment area primary patency in the group that received stent grafts was 27% vs. 14% for the angioplasty group ($p<0.001$); access circuit primary patency was 10% in the stent graft group vs. 6% in the angioplasty group ($p=0.01$), index of patency function was 7.1±7 months/intervention in the stent graft group compared to 5.3±5.2 for the angioplasty group ($p=0.009$). The number of access circuit re-interventions before graft abandonment was 4.3 for the angioplasty group compared to 3.4 for the stent graft group. "Patients who received angioplasty were allowed to receive the stent graft at subsequent intervention," Haskal said.

"There were no significant differences in per-patient number nor type of adverse events rates among the groups, including infection, pseudoaneurysm, or thrombotic occlusion (36.4% in the angioplasty group, 43.5% in the stent graft group, $p=0.26$). Access circuit stenosis warranting intervention occurred significantly more often in the angioplasty group (82.6%) vs. the group receiving stent grafts (63.0%, $p<0.001$)," Haskal told delegates.

Best abstracts selected at CX

For the first time, this year the Charing Cross Symposium featured two Abstract sessions—Physicians Presentations and Posters, and Vascular Trainees, Scientists and Nurses Presentations and Posters.

In the Vascular Trainees, Scientists and Nurses Presentations and Posters session, the chairmen, Alun Davies and Richard Gibbs, chose the top three abstracts, and the presenters were awarded prizes. The first place prize was awarded to David Sidloff (Leicester, UK) for "Aneurysm global epidemiology study: Public health measures can further reduce mortality from thoracic aortic disease". The second place prize was presented to Sarah Onida (Middlesex, UK) for "Trainees on the new vascular specialty programme – who are they?". The third and final prize was awarded to Adnan Bajwa (London, UK) for "A novel blood oxygenation level dependent magnetic resonance imaging strategy for assessing muscle perfusion in the ischaemic limb".

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Carrie White from Vascutek and David Sidloff

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Better patency rates for Zilver PTX compared with bare metal stent in longer lesions

Thomas Zeller (Bad Krozingen, Germany), reporting on the results of two post-market studies at the Charing Cross Symposium (5–8 April 2014, London, UK), said that while both the paclitaxel-eluting Zilver PTX stent and the bare metal Zilver Flex stent are associated with high rates of primary patency in long femoropopliteal lesions, the Zilver PTX has a higher rate of primary patency than the Zilver Flex stent.

Zeller reported that studies have indicated that both stents were associated with good rates of primary patency for the management of patients with lesions in the femoropopliteal artery but added that there are less data for the stents in long lesions. He explained that two post-market studies looked at, respectively, the use of the Zilver PTX (in 45 lesions) and the Zilver Flex (in 55 lesions) in patients with long lesions. In both studies, patients (from multiple investigative sites across Europe) were enrolled if they had de novo or restenotic lesions. Zeller noted: "Follow-up for both studies included 12-month event-free survival and primary patency by duplex ultrasound core laboratory (peak systolic velocity ratio <2)."

The mean lesion length—which Zeller described as being "pretty long" in both studies—in the Zilver PTX study was 189±91mm and was 221±51mm in the Zilver Flex study. He noted that the lesions treated in the studies were "more complex" than those treated in previous studies of the Zilver stents. He explained: "Of the lesions treated with Zilver PTX stents, 82.2% of lesions were totally occluded and 40% of lesions had severe calcification. Of the lesions treated with Zilver Flex stents, 83.6% of lesions were totally occluded and 72.7% of lesions had severe calcification."

At 12 months, there was no device- or procedure-related mortality in either study—Zeller commented: "When using a stent in a longer lesion, you have to ask if it is safe. I would say that it is if performed by an experienced operator." Also at 12 months, event-free survival was 86.1% with Zilver PTX and 85.1% with Zilver Flex.

"Stent integrity was very high for the Zilver PTX with no stent fracture (of 93 implanted stents) whereas there were two stent fractures in the Zilver Flex arm," Zeller noted. He added that the primary patency rates were higher in the Zilver PTX study than in the Zilver Flex study—86.1% vs. 70.5%, respectively. According to Zeller, although no outcome data are currently available, longer term data will show a difference in outcome between the two stents (in favour of Zilver PTX).

Thomas Zeller

Michael Dake (Stanford, USA) also presented data for the Zilver PTX compared with a bare metal stent yesterday. He reviewed four-year data from a randomised-controlled trial. Dake explained that in the trial, the Zilver PTX was compared with percutaneous transluminal angioplasty for the management of de novo or restenotic lesions in the superficial femoral artery. He added that patients in the balloon arm who experienced complete failure (eg. ≥30% residual stenosis) underwent secondary randomisation to provisional stenting with the Zilver PTX or a Zilver bare metal stent. Dake commented: "The 12-month primary endpoints were met and showed non-inferior event-free survival and superior patency for the Zilver PTX group compared to the percutaneous transluminal angioplasty control group. The randomised comparison of provisional stenting with Zilver PTX vs. Zilver bare metal stent also showed significant benefit of the paclitaxel coating."

At the four-year follow-up point, the freedom from target lesion revascularisation rate was significantly higher for the Zilver PTX group compared with the standard care group (83.2% vs. 69.4%, respectively; p<0.01), which included patients undergoing optimal percutaneous transluminal angioplasty and those undergoing provisional bare metal stenting. The four-year patency rate was also superior for the Zilver PTX group compared with standard care—67.6% vs. 45.5%, respectively, p<0.01".

Dake noted: "Provisional stenting with Zilver PTX vs. Zilver bare metal stenting continues to demonstrate significant benefit of the paclitaxel coating through four years, with patency rates of 75% and 57.9%, respectively (p=0.04). The four-year results of this randomised, multicentre trial support the sustained safety and effectiveness of the Zilver PTX drug-eluting stent with no evidence of late catch-up."

Randomised FINEST trial shows new bioactive vascular graft outperforms standard graft in lower limb bypass

The Fusion Bioline vascular graft shows high patency rates in bypasses above and below the knee according to the initial results of the randomised FINEST trial. Data from the study were presented by Afshin Assadian, Vascular and Endovascular Surgery, Wilhelminenspital Vienna, Vienna, Austria, at a Maquet Satellite Symposium in the Charing Cross Symposium.

Speaking about advances in open surgery, Assadian told delegates that the Fusion graft is a combination of a standard PTFE graft with Dacron inner and outer lining and glued together with polyurethane. "This gives the graft very specific properties: haemostatic multilayer design, bioactive luminal lining with heparin and the potential of a bioactive external lining with silver and/or triclosan, representing a shift towards a more autologous vein-like graft than the grafts we had in the past by means of infection and also patency."

The performance of the Fusion Bioline vascular graft was assessed in the randomised FINEST (Comparison of safety and primary patency between Fusion vascular graft with Bioline and Exxcel Soft ePTFE) trial. The study enrolled 209 patients between May 2010 and June 2012 in the USA. Of the total number of patients, 207 were treated, 206 were included in the safety analysis and 203 were included in the efficacy analysis. In the efficacy analysis, 103 patients were treated with Fusion Bioline and 100 with the standard PTFE graft. The six-month follow-up results were used to obtain the FDA 510(k) clearance. The trial principal investigator is Alan Lumsden.

The study included patients with claudication, rest pain and superficial ulcers, and the major inclusion criteria were requirement for femoropopliteal above- or below-the-knee bypass, proximal anastomosis on the most distal external iliac artery, common femoral artery or superficial femoral artery, and Rutherford category 1–5. Patients with previous bypass graft in the same limb were excluded from the trial. Follow-up was performed up to one year.

Afshin Assadian

Presenting the results, Assadian noted that patients presented with standard comorbidities, the majority had the proximal anastomosis in the common femoral artery (94% in the standard PTFE group and 96.1% in the Fusion Bioline group), and more than 85% had the distal anastomosis above the knee. "As only 14% of the patients had distal anastomosis below the knee, it was not possible to draw conclusions about this graft below the knee; the study only gives us a hint," Assadian said. He added: "What is also important is that the use of local haemostatic agent was double in the standard PTFE group (64%) than in the Fusion Bioline group (30.1%). Time to suture hole haemostasis was shorter in the Fusion Bioline group (3.5 minutes) than in the standard PTFE group (11 minutes, p<0.001), even though the amount of haemostatic agent was higher in the standard PTFE group, so the effect of the graft's haemostatic property has definitely been proven".

Six-month data from the study showed superior rates with Fusion Bioline for primary patency (86.4% vs. 70%), primary-assisted patency (86.4% vs. 73%) and secondary patency (88.3% vs. 80%). "We can see a 16-percentage point absolute difference for patency at six months. In other words we would have to treat approximately six patients with Fusion Bioline to avoid one occlusion at six months—so this is clinically relevant," he said.

PERFECTION trial

Assadian also presented results of the Fusion vascular graft (without heparin) in the PERFECTION trial, a single-arm study comparing the performance of the graft to historical data in German centres. "The study aimed at enrolling 150 patients, but after a safety analysis of 80 patients we decided to stop the study due to unexpected good results," Assadian said.

He told delegates that PERFECTION enrolled patients with claudication, rest pain and superficial ulcers and only above the knee disease, without problems with their iliac or popliteal arteries, therefore "a different population" from those included in the FINEST study.

The results showed that, at 12 months, primary patency was 87.3%, primary assisted patency was 88.2% and secondary patency was 94.1%. "The benefits were also translated into clinical improvement at one year, as the vast majority of the patients shifted to Rutherford categories 0 and 1," Assadian said. "We see an excellent primary patency with both Fusion and Fusion Bioline grafts, as well as excellent biocompatibility. We hardly had any issues such as seromas or haematomas and that is most likely due to the fact that the graft has a haemostatic structure. These grafts are certainly a promising platform for external and potentially different internal bioactive surfaces."

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1. Dake MD, Ansel GM, Jaff MR, et al. Sustained safety and effectiveness of paclitaxel-eluting stents for femoropopliteal lesions: 2-year follow-up from the Zilver PTX randomized and single-arm clinical studies. J Am Coll Cardiol. 2013;61(24):2417-2427.

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Pelvic vein reflux could cause haemorrhoids, suggests study

Women with significant pelvic vein incompetence are likely to have haemorrhoids, which could suggest a causal link, according to research from a varicose vein clinic.

Judy Holdstock (Whiteley Clinic, London) told the Charing Cross Symposium that pelvic vein incompetence was a common problem, affecting approximately 20% of women with leg varicose veins. Of 56 women with both pelvic vein incompetence and haemorrhoids studied via transvaginal scan at the clinic, virtually all had reflux in both internal iliac veins and one-third also had involvement of the left ovarian vein.

Holdstock told the meeting: "Haemorrhoids are associated with the more extensive patterns of trunk reflux and more importantly are associated directly with internal iliac reflux." However, she said it was not clear whether the haemorrhoids were caused by pelvic vein reflux, whether they were exacerbated by pelvic vein reflux, or if this was an incidental finding.

The review was conducted among 593 female patients with varicose veins presenting to the clinic over one year, of whom 153 were scanned transvaginally because of a reflux pattern suggestive of pelvic involvement. Holdstock commented that women with varicose veins frequently have symptoms suggestive of pelvic venous congestion: "Many report the symptoms of pelvic congestion syndrome ranging from throbbing and aching in the lower back to irritable bowel and bladder, and dyspareunia, and many report a history of haemorrhoids."

Transvaginal scans were conducted with the patient supine with their head and torso elevated to 45 degrees, using colour flow Doppler and asking them to perform the Valsalva manoeuvre to test for reflux. The sonographers assessed internal iliac veins, ovarian veins, perianal veins and haemorrhoids, looked for reflux of greater than one second in trunks and tributaries of over 5mm, and persistent reflux in tributaries or trunks of less than 5mm. They also looked for the dilation of venous trunks on Valsalva.

Of women given a scan, 113 (74%) were found to have significant pelvic vein incompetence, and 56 (36%) had haemorrhoids. Holdstock said: "Initially we thought we would be looking at an ovarian vein nutcracker phenomenon; however, this is seen in less than 5% of our series."

Judy Holdstock

Assessment of venous competence revealed that reflux was more significant in each of the pelvic trunks in the 56 women with haemorrhoids compared to the 97 without. Eighty five per cent of those with haemorrhoids had right internal iliac vein involvement compared to 52% of those without, while left internal iliac vein involvement was apparent in 82% of the women with haemorrhoids compared to 53% of those without. The left ovarian vein was involved in 73% of the women with haemorrhoids compared to 39% of those without.

Holdstock said: "When we looked at the statistics in the haemorrhoid group a third of them had that three-vessel pattern, virtually the entire group had involvement of both internal iliac veins with no patients having reflux in ovarian veins only in this group. Comparing the haemorrhoid to non- haemorrhoid group, reflux was more significant in each of the pelvic trunks in the haemorrhoid group."

Holdstock said the clinic was now going to conduct a prospective study in which a colorectal surgeon would refer female patients with symptomatic haemorrhoids for transvaginal ultrasound to assess pelvic vein reflux.

She commented that among all 153 women who were scanned, the most common pattern was for three-vessel involvement: "Both internal iliacs are the most common to reflux, the least common being the right ovarian. The most common patterns we find are bilateral internal iliac vein involvement and the left ovarian in a quarter of the group. Ten per cent of the group have failure of all four veins. Isolated left ovarian vein reflux was present in only 1.3% of the group."

Large, strong, flexible stents are the key to successful venous reconstruction

Stents used for venous reconstruction should be large, crush-resistant and flexible enough to accommodate curves and potential pinch points, Gerry O'Sullivan (University College Hospital, Galway, Ireland) told delegates at the Charing Cross Symposium (5–8 April 2014, London, UK).

O'Sullivan said that that iliac venous stent patency was equivalent to or better than arterial stent patency, but placing venous stents was a "different game to arterial". They needed to be of a large diameter, over 14mm, in order to work properly, and balloon dilatation pre- and post-stent implantation was essential.

He explained: "Veins rarely rupture. If I have an 85-year-old woman with arterial disease, you would think about putting in maybe a 6mm or 7mm diameter arterial stent, [but] in that same woman, if she gets a deep vein thrombosis, I will put in a 16mm venous stent and I will not rupture the vein. It is a different pathology, there is not atherosclerosis, there is no rupture of plaque, you have got to stretch them to a big diameter because it is a low-pressure system."

He emphasised to delegates that experience had taught him to use larger stents and full dilation: "You must dilate the stents fully. I know from my own data that if we stopped at 12mm or less, the thrombosis rate is three times than if it is 16mm, so you have to go big."

In venous stenting, unlike arterial stenting, he said pain was "not a sign of impending rupture" and operators should not stop dilation because the patient was experiencing pain. He said that pain was normal and a general anaesthetic was often required.

He added that stents needed to resist compression and extend from flow to flow regardless of anatomical constraints such as the inguinal ligament. He said: "The stent has got to have enormous crush resistance, if you put in a soft arterial stent it will get crushed." The presence of compression points meant the stent needed to have a combination of crush resistance and flexibility. O'Sullivan said: "We are looking at big, powerful, flexible stents, completely different to what you are used to in iliac arterial disease."

Of the stents available, O'Sullivan said the Wallstent (Boston Scientific) was most commonly used and had proven to be an "excellent workhorse" and in the hands of expert operators achieved patencies that were better than arterial at 10 years. Problems with the Wallstent included that it could be difficult to land precisely, there could be foreshortening and the end could pinch.

He said the Zilver Vena (Cook Medical) had been the first venous-designed stent to come to market and was precise and flexible although radial hoop strength could be a potential problem. He said the Optimed Sinus platform offered a variety of solutions for stenting in different locations, with excellent radial hoop strength, while Veniti had just launched the Vici, which offered good radial hoop strength with some foreshortening. O'Sullivan said: "One of the big advantages of the new stents, whether it is the Zilver Vena, Sinus or Vici, they are very precise and deliverable over the horn quite accurately." However, he observed that the Vici, like all of the other newer stents, was more expensive than the Wallstent.

He concluded that: "Venous stenting is here to stay. Compared to four years ago, before the introduction of the first venous-designed stents, we now have stents that are much better designed, bigger, longer, stronger with good flexibility, so I think we are going in the right direction."

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Evidence for deep venous reconstruction is "extremely weak"

Stephen Black, St George's Hospital, London, UK, told delegates at the Charing Cross Symposium (5–8 April 2014, London, UK) that most of the evidence for deep venous reconstruction is based on single-centre experiences, many of them small, and therefore "extremely weak".

In his presentation, Black explained that the basis of analysing patients with deep venous disease is the CEAP classification, Villalta Score and the Venous Severity Score. However, he said, these tools do not provide a full picture of many patients who are treated for deep venous disease, "with no real understanding of the haemodynamic mechanisms of bringing these patients to be treated in the first place, and in addition these scores are based entirely on signs and symptoms."

The same applies to the use of imaging, according to Black, where there is a lack of consensus whether CT or MRI is the best modality to assess deep venous disease patients. "The bottom line is that these are all axial image modalities with patients generally lying on their back so they do not provide us with information of the haemodynamics of the circulation. And the use of imaging ultimately ends up depending on what you have available in your institution, so you have to be slightly pragmatic," he said, adding that at St George's Hospital he uses CT.

He noted that the same applies to the use of IVUS and venography, and added: "With IVUS, the consensus seems to be that it is expensive and there has not been any evidence of whether it is a useful tool, so we do need to establish if IVUS is going to make any difference to our patients' treatment. I have found it an indispensable tool for seeing exactly what the stent looks like after placement and making sure that I do not leave any residual stenosis, particularly if I am looking for residual clot or any other lesions that need treating after lysis. In addition IVUS has the potential to significantly reduce the radiation dose administered to the patient."

Stephen Black

Black then described the treatment pathway of deep venous reconstruction. "You treat the obstructive component first—whether it is proximal or distal, you want to eliminate the obstruction in the system—and the mainstay for this is going to be stenting (in this day and age bypass is reserved for patients with occluded stents or those who have significant symptoms that require an operation). You then treat the superficial reflux, and endovenous ablation will be the mainstay of that. Finally, you deal with the deep venous reflux that is left behind. Neglen and Raju say only approximately 5% of patients ever come to need any form of valve reconstruction," he said.

Stenting in chronic patients, according to Black, achieves good results. He showed delegates the case of a patient treated with the Veniti stent and said that once the lesion was crossed and the stent was placed, there was a good resolution of symptoms. However, he said, "we rely a lot on Neglen *et al* (J Vasc Surg 2007;46:979–90) and Raju and Neglen (J Vasc Surg 2009;50:360–8) long-term data to provide us with any evidence for this," and added, "An important take-home message with stenting of both chronic lesions and post-thrombotic lesions is that the patency rates are assisted primary and secondary. If you rely entirely on putting a stent and never following up your patient, a lot of these stents will block and you will have very poor patency rates."

Black moved on to talk about patients for whom bypass surgery is the only treatment option. He showed the case of a femoro-caval bypass in which the patient had a stent that occluded and who presented with venous claudication and significant C6 lesions that were not healing. "Bypass procedures work well but are time consuming and you have to work hard to keep them patent. In addition, fistulae are still a controversial area where we are not entirely clear whether they are effective or not. In this particular patient, six months after his procedure, the bypass is still patent and the symptoms have improved markedly, but you have to be very careful in your patient selection; they need very good inflow otherwise there is no point in even attempting a bypass," Black said.

He added that the results of bypass surgery also rely on single-centre experiences. "You certainly can get good results, but these are dependent on interventions as primary patency rates are poor. You have to be intervening in these patients, dealing with complications and following them up very carefully."

In relation to valve reconstruction, Black said it is "perhaps the trickiest and most difficult part of deep venous intervention". He added: "I spent some time with Oscar Maletti in Italy and his procedure for Neovalve reconstruction is a beautiful operation. He is an artist with this procedure and I do not know how extrapolable that operation is. Again we rely heavily on single-centre experience and mostly Kistner for primary valvuloplasty. Primary valvuloplasty is better than external valvuloplasty and you can reserve Neovalve for those more difficult cases. Endovenous techniques for valve replacement are on the way but nothing yet is suitable for valve reconstruction."

The conclusion, Black said, is that we are in an era where evidence for deep venous reconstruction is extremely weak but advancing. "There are lots of single-centre experiences, but it is very difficult to interpret the data. We need to understand the haemodynamics of the deep venous system much more carefully than we do and we need to understand the relationship between the deep and superficial systems. We also need to understand what the passage from an asymptomatic patient with a May Thurner lesion and no problem to somebody with obstruction is and we need to clarify things like the role of IVUS and imaging in this disease."

VVCVV trial abstract awarded second place at Royal Society of Medicine Venous Forum

An abstract on the randomised VVCVV (Venefit versus ClariVein for varicose veins) trial was placed second in the top winners for innovative abstract at the Royal Society of Medicine Venous Forum Annual Spring Meeting (23–24 April 2014, London, UK). Tristan Lane, Imperial College London, UK, presented the abstract.

Radiofrequency is one recognised and established method of office-based vein practice for the correction of superficial varicose veins. ClariVein, or mechanochemical ablation (MOCA), is an alternative technology.

VVCVV is an ongoing trial and is comparing the two treatment modalities—radiofrequency with the Venefit system from Covidien and mechanochemical ablation with the ClariVein system—with the primary endpoint of pain during the procedure. The trial is being performed in two centres; the target recruitment is 170 patients and the trial is in active recruitment.

Alun Davies, Imperial College London, UK, principal investigator of the trial, explained that "mechanochemical ablation involves using a catheter that is inserted into the vein under ultrasound control, a sclerosant is then injected via the catheter and at the same time of the injection, the tip of the catheter rotates, damaging the lining of the vein, allowing the sclerosant to get into the vein wall to make it shrink down."

The preliminary, 30-day results presented by Lane at the Venous Forum Spring Annual Meeting were on periprocedural pain reported by the patients, Davies said.

Davies told *Vascular News*: "The preliminary results that we have seen are that during the procedure, the pain scores are significantly better in those patients treated by MOCA versus those treated by radiofrequency ablation. However, at one month, the clinical and quality of life scores in both groups are the same."

The trial will assess patency and occlusion rates at six months and one year, and also quality of life measures. According to the principal investigator, the final results, including occlusion rates, will probably be presented in the first or second quarter of 2015.

Is all heat the same and does catheter design matter?

MARK S WHITELEY

COMMENT & ANALYSIS

Since the NICE (National Institute for Health and Care Excellence) guidelines for the treatment of varicose veins was published in July 2013, endovenous thermal ablation has now "come of age". Recommended as the first line treatment for symptomatic varicose veins of truncal origin, it is essential that every doctor practising varicose vein surgery has a good understanding of the principles of endovenous thermoablation.

This is particularly important as there are different technologies and a wide range of different products, all labelled "catheter-based endovenous thermoablation". Provided we understand the principles, then it becomes easier to ensure excellent results regardless of the technology generating the heat.

The general principles of thermoablation can be boiled down (no pun intended) to a few concepts, working through which we can answer the question posed in the title.

Firstly, at a very basic level of physics, heat is heat and in endovenous surgery, it is all basically the same. Although temperature was thought to be important in the early days of endovenous thermoablation when people thought collagen contraction was the mechanism of venous closure, we now measure the total energy transferred to the vein wall in joules per centimetre of vein. This is called the LEED—the Linear Endovenous Energy Density.

However, an optimal LEED achieved in a vein treatment by itself does not guarantee successful ablation of the target vein. If blood or excess fluid remains within the vein lumen, the measured energy transmitted from the thermoablation device will not all reach the vein wall, resulting in inadequate treatment despite a seemingly normal LEED.

Furthermore, the thermal energy introduced via the endovenous catheter must be applied at a rate that allows diffusion of the heat energy through the vein wall, allowing complete transmural treatment without causing tissue carbonisation at the intima which might act as a barrier to heat energy penetrating the vein wall, result in the endovenous device getting stuck to the vein wall. Thus total heat energy getting into the vein wall, the rate at which it is applied and the distribution of the heat within the vein wall are all essential components of successful endovenous thermoablation.

Turning to catheter design, the simple answer is "yes"—it does matter. The basic requirements that all endovenous thermoablation catheters require are the ability to be passed up the lumen of the target vein, to be able to be imaged to ensure accuracy of treatment, to have markings on the shaft to ensure proper pull-back protocols depending on the method being used and then the ability to pass thermal energy into the vein wall.

This last point, the treatment "tip" is of course the most important part of the catheter design. Depending on the technology used, the tip might need direct contact with the vein wall for thermal conduction, such as in the hot tip of the Venefit (formally VNUS Closure FAST), or just contact for heat to be generated by the passage of alternating currents at radiofrequency rates, such as with the bipolar RFiTT or the monopolar EVRF.

Of course with laser and steam, direct contact is not required, but the way the energy is radiated, forward firing or radial firing for laser or orientation of ports with steam, dictate the tip design.

Thus for successful endovenous thermoablation, sufficient heat energy needs to be transmitted to the vein wall in an optimal manner, and catheter design and technique of use are essential to get optimal results.

Mark S Whiteley, The Whiteley Clinic, Guildford, UK

Self-reported complication rate among retrievable inferior vena cava filters is significantly higher than permanent devices

Findings from a review of the United States Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database reveals that complications occur with significantly higher frequency in retrievable inferior vena cava filters compared to permanent filters.

Investigators Interventional Radiology section at Northwestern University in Chicago told delegates at the Society of Interventional Radiology's 39th Annual Scientific Meeting (22–27 March, San Diego, USA) that they aimed to compare the safety of permanent and retrievable inferior vena cava filters by reviewing the self-reported complications of these devices in the MAUDE database from January 2009–December 2012.

Jessica Andreoli, radiology resident at Northwestern University, Chicago, USA, explained that she recorded the total number of inferior vena cava filter complications self-reported to the MAUDE database during the study period; she specifically categorised the complications by type and rate for all available devices on the market.

The results of the study showed that there were 1,606 reported adverse events involving 1,057 filters. There were 1,394 (86.8%) adverse events involving retrievable IVC filters and 212 (13.2%) that involved permanent IVC filters ($p<0.0001$). The number and percentage of each specific adverse event was higher in retrievable inferior vena cava filters when compared to permanent filters. The prevalence of each specific complication varied widely among brands. The most commonly reported adverse events were: fracture (27.1%) for Bard (Bard) devices, inferior vena cava penetration (29.9%) for Celect (Cook), placement difficulties for Optease (Cordis)(30.8%) and Gunther Tulip (Cook)(45%).

Robert K Ryu and Robert J Lewandowski

"This study suggests that optional filters are inferior to permanent devices in terms of self-reported, device-associated complications," Andreoli concluded.

Robert J Lewandowski and Robert K Ryu, also from Northwestern University commented: "Retrievable inferior vena cava filters were developed to protect patients against fatal pulmonary embolism, y*et al*low for their removal when no longer indicated. The engineering intent of retrievable filters compared to permanent devices was to be less stable and lower profile so they could be easily removed. The advantage inherent in being retrievable has rendered these filters to be more prone to device-related complications like migration, fracture, and perforation. Recognising the growing epidemic of device-related complications, the FDA issued a 2010 "Initial Communication" regarding the risk of adverse events associated with long-term use of retrievable filters.

"Our review of the MAUDE database confirms the differing characteristics of permanent and retrievable inferior vena cava filters. The challenge going forward is to optimise the utilisation of both permanent and retrievable inferior vena cava filters, recognising that there is continued need for both types of devices. Patient care and resource utilisation is optimised when careful prospective decision-making is carried out, as well as meticulous follow-up after filter placement. Further, safe and effective use of ancillary techniques to remove retrievable devices is advocated."

Commentary

Michael Lee, consultant interventional radiologist and professor of Radiology, Beaumont Hospital Radiology Department, Dublin, commented:

"Andreoli *et al* present reported inferior vena cava filter complication rates from the

Continued on page 37

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Self-reported complication rate among retrievable inferior vena cava filters is significantly higher than permanent devices

Continued from page 35

MAUDE database and show a higher reported complication rate for retrievable filters when compared with permanent filters. In total, there were 1606 reported complications between 2009 and 2012 with 212 complications reported for permanent filters and 1394 reported for retrievable filters. However, we do not know how many permanent and retrievable filters were placed during this time period. Over the last 10 years many more retrievable filters are placed compared to permanent filters. Therefore, the overall complication rate for retrievable filters placed is unknown in this study.

The CIRSE Retrievable IVC filter registry reported on 628 retrievable filters placed at CIRSE 2013. There were two major complications (<1%) and 14 minor complications (2%).

In addition, the significance of the complications reported to the MAUDE database are unknown. For instance, we do know that inferior vena cava penetration (214 events reported for retrievable filters)

Michael Lee

is usually asymptomatic. It is unclear what the significance of placement issues (reported at 219 events) means. Were these failed placements (unlikely) or technical difficulties related to unfamiliarity with the kit or inexperience on the part of the operator? We also do not know whether these filters were placed by interventional radiologists or other specialties. Similarly, inferior vena caval thrombus is always going to be reported more frequently with retrievable filters than with permanent because thrombus is going to be imaged at retrieval. Many of these are dealt with at the time of retrieval without the need for prolonged hospitalisation. The most significant events reported of filter fracture, migration and limb embolization were mainly associated with one filter type which has since been withdrawn from the market. Filter tilt (194 events), may or may not significant depending on whether the degree of tilt hinders retrieval or not. Interestingly, the number of reported venous thromboembolism/pulmonary embolism events reported (eight for permanent and 22 for retrievable) are low, indicating that filters are fulfilling their primary function.

In summary, this is an interesting study which should be interpreted with caution. A list of reported complications without the denominator of the total number of filters placed is but a snapshot. The significance of the events listed are also unknown making is difficult to draw any meaningful conclusions. The study does however, point out the deficiencies associated with some filter designs and the lack of level 1 evidence associated with inferior vena cava filter use."

FDA approves new anticoagulant for venous thromboembolism

The FDA has approved dabigatran etexilate mesylate (Pradaxa, Boehringer Ingelheim) for the treatment of deep vein thrombosis and pulmonary embolism in patients who have been treated with a parenteral anticoagulant for five to 10 days, and to reduce the risk of recurrent deep venous thrombosis and pulmonary embolism in patients who have been previously treated.

The approval is based on results from four global phase III studies evaluating the efficacy and safety of dabigatran in the treatment of deep venous thrombosis and pulmonary embolism.

The RE-COVER and RE-COVER II trials, which included patients with deep venous thrombosis and pulmonary embolism who were treated with parenteral anticoagulant therapy for five to 10 days, showed dabigatran was non-inferior to warfarin in reducing deep venous thrombosis and pulmonary embolism after a median of 174 days of treatment, and was associated with lower rates of overall bleeding and a higher rate of any gastrointestinal bleeding (3.1% vs. 2.4%). RE-MEDY(SM), which included patients who had been previously treated for an acute deep venous thrombosis and pulmonary embolism with anticoagulant therapy for three to 12 months, showed dabigatran was non-inferior to warfarin in reducing deep venous thrombosis and pulmonary embolism after a median of 534 days of treatment, and was associated with lower rates of overall bleeding and a higher rate of any gastrointestinal bleeding (3.1% vs. 2.2%).

RE-SONATE, which included patients who had been previously treated for an acute deep venous thrombosis and pulmonary embolism with anticoagulant therapy for six to 18 months, showed dabigatran reduced the risk of deep venous thrombosis and pulmonary embolism recurrence by 92% compared to placebo after a median of 182 days of treatment: 0.4% vs. 5.6%; HR = 0.08 [CI 0.02, 0.25]. Dabigatran was associated with higher rates of any bleeding (10.5% vs. 6.1%; HR = 1.77 [CI 1.20, 2.61]), clinically relevant non-major bleeding (5.0% vs. 2.0%; HR = 2.54 [CI 1.34, 4.82]), and gastrointestinal bleeding (0.7% vs. 0.3%) compared to placebo.

Product News

Anaconda abdominal aortic aneurysm stent graft system approved for expanded indication

Vascutek has announced that it has received CE mark approval for Anaconda to be used to treat infrarenal abdominal aortic aneurysms in patients with proximal aortic neck angulation of ≤90 degrees providing a clinical solution for patients with tortuous anatomy.

The Anaconda stent graft is designed to deliver exceptional flexibility with innovative ring stent technology to provide a proactive sealing system which conforms to the natural anatomy of the patient.

The ability to fully reposition enables clinicians to deliver the system accurately to the target even in challenging anatomy.

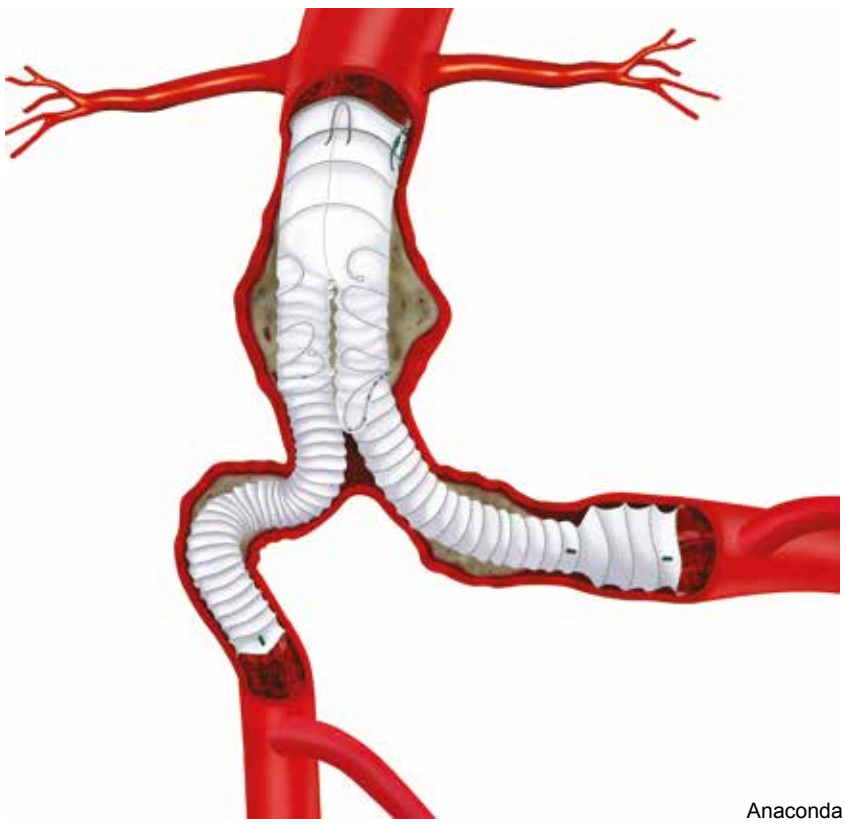
Vascutek's vice-president of Sales, Marketing and Clinical Services, Alan Rogers, says: "As EVAR techniques have evolved over the years, Anaconda has provided clinicians with a solution for a wide-range of patient anatomies."

In March, Vascutek announced the return to market of the Anaconda bifurcate body stent graft system for patients with abdominal aortic aneurysms. The system was voluntarily recalled in October 2013 following the identification of a potential issue with the release wire in the delivery system.

Vascutek has worked closely with its UK Competent Authority, Medicines and Healthcare products Regulatory Agency, and notified body, British Standards Institution to review the plans for return to market and, having satisfied the regulatory requirements, Anaconda can now be released for clinician use.

Vascutek president and chief executive officer, Paul Holbrook, says: "Our development work at Vascutek is all about the patient, putting the highest standards of patient safety and product quality at the forefront of all we do. We are pleased that this popular system can now return to use. We are working hard to get stock to where it is most urgently needed first, and we are in discussions with customers to manage this whilst stock levels begin to return to normal over the coming months. We have been overwhelmed with support from the medical community across the globe as we investigated this issue. We would like to thank everybody for their understanding and patience during this time."

The Anaconda stent graft system is used to treat abdominal aortic aneurysms. More than 17,000 Anaconda stent grafts have been implanted since the system was launched in 2005.



Anaconda

E-ventus BX peripheral balloon expandable stent graft receives the CE mark

On 10 February 2014, Jotec received CE approval of a next generation balloon expandable peripheral stent graft system indicated for interventional therapy of renal and iliac arteries in cases such as ruptures, dissections and aneurysms.

According to Jotec, the new E-ventus BX excels in maximum stent graft flexibility to conform to the native vessel's curvature. The stent graft consists of a microporous, single-layer ePTFE and a unique cobalt-chromium stent design for high radial strength together with MRI compatibility. The E-ventus BX stent graft can be deployed to the specified diameter with minimal recoil and foreshortening as well as securely anchored within the target vessel. The flexible delivery system facilitates advancement into the vessel for safe and convenient stent graft deployment with a low profile of 6F for 5 and 6mm stent grafts and 7F for 7 to 10mm stent grafts. The stent graft is available in lengths from 18 to 58mm in several steps.

The E-ventus BX is European wide commercially available with immediate effect.

E-ventus

Terumo receives the CE mark for the Roadsaver carotid artery stent

Terumo has announced it has expanded its Peripheral Vascular Solutions portfolio towards the treatment of carotid arteries. According to the company, the Roadsaver Carotid Artery Stent, a double layer micromesh stent, manufactured by MicroVention, a subsidiary of Terumo, has received the CE mark.

In a press release, Terumo said the Roadsaver stent is indicated for use in patients with carotid arterial atherosclerotic disease, by combining three unique features to further advance carotid artery stenting:

The stent is made of a dual-layer micromesh scaffold with the smallest cells of any carotid stent available in Europe. The Roadsaver is designed to sustain embolic protection much like a covered stent but y*et al*lows patency to side branches.

The braided nitinol design also provides the physician with a closed cell stent having the wall apposition and flexibility of an open cell design. This allows the stent to be adaptable to most carotid anatomy.

The very flexible stent delivery system can be recaptured up to 50% deployment length and the stent can be repositioned for accurate placement. Due to its flexibility the stent delivery system perfectly tracks through tortuous anatomy towards the lesion, minimising the risk of access sheath/guide catheter dislodgement.

TriVascular announces FDA-approved expansion of Ovation and Ovation Prime indication statements

On 29 April 2014, TriVascular Technologies announced FDA-approved changes to the indication statement for the Ovation and Ovation Prime Abdominal Stent Graft Systems (Ovation system).

The expanded indication for use statement eliminates the minimum aortic neck length requirement and also includes clarification on appropriate vascular access techniques. The Ovation Abdominal Stent Graft System received FDA PMA approval in October 2012. The PMA-S approval for the Ovation Prime Abdominal Stent Graft System followed in December 2012.

According to TriVascular, the Ovation system, with its unique sealing technology, is now the only FDA-approved EVAR stent graft that is not restricted by the conventional measurement of aortic neck length in its labeling. The Ovation system utilises an innovative, polymer-filled sealing ring that does not exert chronic outward force, and protects the aortic neck from dilatation by insulating it from the force of blood pressure. Unlike conventional self-expanding stent grafts, the Ovation system does not require a minimum length of parallel vessel walls in order to achieve aneurysm seal. The sealing ring provides circumferential seal at a specified location in the aorta. The clarified indication statement provides that the Ovation system may be used when the inner wall diameter is no less than 16mm and no greater than 30mm at 13mm below the inferior renal artery.

Neck length is only considered in assessing angulation: patients with a proximal neck length of less than 10mm are indicated with an aortic angle of less than or equal to 45 degrees; otherwise angles up to 60 degrees are indicated.

"I am pleased to see the recent update to the Ovation system indications for use. This provides support that TriVascular's innovative sealing ring technology is very different from conventional stent grafts, and provides the less invasive solu-

Product News

tion, even in patients with hostile aortic neck anatomy," commented Manish Mehta, director of Endovascular Services at the Vascular Institute for Health & Disease in Albany, USA, who was the principal investigator for the Ovation pivotal clinical trial. "The pivotal trial clinical results out to two years are excellent, and include data demonstrating complete absence of aortic neck dilatation."

The expanded indication statement also includes a clarification that both percutaneous access and femoral cutdown are appropriate vascular access techniques. The option for either percutaneous or femoral cutdown was already approved in the prior Indications for Use. This change includes the word percutaneous directly in the indication statement. Examining an available database of 43,000 patient scans, 85% of those patients had an aortic neck length and access vessel diameter within the Ovation system's revised indication statement.

"The recent approval from the FDA serves as a testament to the novel, innovative approach that the Ovation system offers and serves to increase the patient population suitable for EVAR with the Ovation system," said Christopher G. Chavez, chairman, CEO and president of TriVascular. "Based on a minimum neck length requirement of conventional self-expanding stent grafts and their associated system profile of 18F OD or greater, the majority of diagnosed abdominal aortic aneurysm patients did not have an on-label option for EVAR prior to FDA approval of the Ovation system. With the Ovation system's innovative sealing ring technology and ultra-low profile 14F OD system, a majority of diagnosed abdominal aortic aneurysm patients now have an on-label, clinically proven solution."

The Ovation system has been used in the successful treatment of over 3,500 patients worldwide. According to TriVascular, excellent clinical results have been reported from both the Ovation global pivotal trial and a 500-patient European Post-Market Registry. In the pre-market clinical trial, the Ovation system demonstrated 100% freedom from type I and III Endoleaks at two years, as well as no aortic neck dilatation through the two year mark. The Ovation and Ovation Prime systems are available for sale in over 25 countries around the world.

Straub Medical receives the CE mark for the 10F Rotarex S catheter

Straub Medical AG has announced it has received class III CE mark approval for its 10F Rotarex S mechanical debulking catheter. In a press release, the company said that driven by the success story of the 6F and 8F Rotarex S catheters the new 10F version offers a wide range of indications and effective debulking in large lumen arteries (7–12mm diameter) eg. in iliac arteries, stents and in prosthetic stent grafts for endovascular abdominal aortic aneurysm repair.

Supera stent gets FDA approval

Abbott Vascular has announced that its Supera peripheral stent system has received FDA approval to treat patients with blocked blood vessels in the upper leg caused by peripheral artery disease.

According to a company press release, the Supera stent, which mimics rather than resists the artery's natural movement, is an important advancement for many peripheral artery disease patients, helping to ease their leg pain while walking. Its unique, proprietary interwoven wire technology restores blood flow to the treated area, while offering strength and flexibility. Specifically, the Supera stent is now approved to treat blockages in the superficial femoral artery and the proximal popliteal artery.

According to Abbott, compared to other nitinol stents used to treat blocked blood vessels in the upper leg, the Supera stent is more flexible, stronger and resistant to kinks or fracture under vigorous movement.

"Doctors are increasingly identifying peripheral artery disease as a major cause of leg pain, which can limit people's ability to live a healthy lifestyle," says Kenneth Rosenfield, section head

Rotarex S 10F

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Product News

of Vascular Medicine and Intervention at Massachusetts General Hospital and the principal investigator of the SUPERB clinical trial, which evaluated the Supera stent. "Treatment with the Supera stent, as shown by the results of the SUPERB study, is very effective in easing leg pain, enabling the majority of patients to resume their activities."

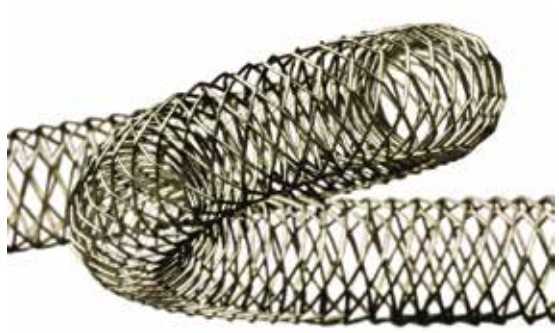
Data from the SUPERB clinical trial, which was used to support FDA approval of the Supera stent, have shown the Supera stent to be highly effective in opening up blocked blood vessels in the upper leg, even in difficult cases, and results have been shown to last over time. In addition, during the first year after treatment with the Supera stent there were no stent fractures, and at two years there was a very low stent fracture rate of 0.5%.

The Supera stent has the CE mark in Europe for treating blocked blood vessels caused by peripheral artery disease.

First patients enrolled in clinical study of drug-coated Chocolate balloon

TriReme Medical has announced that the first three patients were enrolled in a clinical study of its unique drug-coated Chocolate percutaneous transluminal angioplasty balloon. Andrew Holden, co-principal investigator of the study, performed these procedures at Auckland City Hospital, in Auckland, New Zealand.

The drug-coated Chocolate clinical study is a single-arm trial that will enrol a minimum of 30 patients at up to four centres in New Zealand and Germany. The trial will evaluate the rate of procedural success



Supera

immediately after treatment as well as persistence of positive outcomes at six and 12 months post procedure. All key outcomes of the trial will be evaluated by independent core laboratories.

According to TriReme Medical, the drug-coated Chocolate percutaneous transluminal angioplasty balloon is designed for the treatment of patients with vascular disease in their legs, known as peripheral arterial disease. The drug-coated Chocolate percutaneous transluminal angioplasty balloon is unique in that it combines the acute benefits of the FDA and CE approved Chocolate percutaneous transluminal angioplasty balloon with paclitaxel-based coating, an anti-proliferative drug proven to reduce the build-up of tissue in the vessel that can occur months after the original procedure. The underlying Chocolate percutaneous transluminal angioplasty balloon platform has demonstrated a very low rate of dissections and bail out stenting in clinical studies.

"The first three complex cases in this study highlight the advantages of the underlying Chocolate platform in creating a larger and more uniform lumen while minimising vessel trauma," stated Andrew Holden, director of Interventional Services at Auckland City Hospital and associate professor of Radiology at Auckland University School of Medicine, New Zealand.

Arthesys launches new peripheral balloon dilatation catheter

Arthesys has received the CE mark of its Lynx 14 over-the-wire (OTW) percutaneous transluminal angioplasty peripheral balloon catheter. According to Arthesys, the Lynx 14 OTW catheter comes in various options: either as plain dilation catheter, as stent delivery system, or as drug eluting delivery platform.

In a press release, Arthesys stated that the Lynx 14 OTW balloon catheter comes with a unique shaft, allowing for exceptional pushability, and progressive flexibility to reach the most difficult lesions. Balloon design avoids any banana shape, thus providing particularly efficient dilatation, but also unique stent and drug delivery combined with reliable compliance. Hydrophilic coating comes in various options, allowing reaching and crossing stenosis even more effectively.

FDA clears Volcano's iFR Modality

Volcano Corporation has announced US Food and Drug Administration (FDA) clearance of its proprietary instant wave-free ratio (iFR) Modality and immediate commencement of US limited market release.

The iFR Modality is a physiologic measurement performed using the same pressure wires and equipment utilised in cath labs for fractional flow reserve, but avoids injection of hyperemic agents into the patient that induce stress to the heart. This allows for a meaningful, lesion-specific assessment in seconds by amplifying the resting pressure waveform. The iFR Modality is currently installed on more than 300 systems around the world, primarily in Europe and Japan. FDA clearance now means that more than 90% of Volcano's worldwide installed base of multi-modality systems can be upgraded.

"As cardiologists today we are concerned not only with the well-being of our patients, but also about the efficiency with which we deliver appropriate and individualised care for a very complex problem," comments Amir Lerman, co-principal investigator of ADVISE II and professor of medicine at the Mayo Clinic in Rochester, USA. "Stents have proven beneficial when used selectively in patients that demonstrate a functional deficiency, and fractional flow reserve is a terrific tool to identify the specific lesion causing the problem. Instant wave-free ratio will further increase efficiency by reducing the time, cost and complexity required to properly identify lesions causing this functional deficiency, and then confirming the problem is resolved by the stent."

The iFR Modality is used most efficiently with Volcano's recently-introduced Verrata Pressure Guide Wire, which is designed for simple disconnection and reattachment during a procedure, and facilitates making quick measurements multiple times during a procedure without injecting hyperemic agents each time.

"We are extremely excited that both the iFR Modality and Verrata can now be made available to clinicians here in the United States, as the two tools are designed to be used together," comments Joe Burnett, executive vice president and general manager of the Functional Management Business at Volcano. "In Europe, where we are now seeing how physicians use the two technologies alongside fractional flow reserve, the feedback has been very positive. In the past, physicians would place the wire in the vessel, perform an fractional flow reserve to 'justify' the need for intervention, and then return to the angiogram to 'guide' how many stents should be placed and where. Adding the iFR Modality and Verrata to the picture, that same physician can now not only perform fractional flow reserve to identify the vessel that needs treatment, but also can switch to instant wave-free ratio to quickly identify which lesion causes the largest drop in pressure, place a stent, and then reconnect to confirm that the stent helped reduce the pressure drop. This is a workflow that would be very uncommon with older wire technology and the need for multiple drug infusions. This helps to evolve physiology from a justification tool to a guidance tool."

The performance of the iFR Modality has been tested prospectively in approximately 800 patients as part of the ADVISE II (Adenosine vasodilator independent stenosis evaluation) study which was presented as a late breaking clinical trial at Transcatheter Cardiovascular Therapeutics meeting last fall. The iFR Hybrid Approach Analysis performed on the independently-held ADVISE II dataset was the first prospective, real world registry comparing instant wave-free ratio and fractional flow reserve and it demonstrated a statistically high correlation (sensitivity 90.7% for fractional flow reserve less than or equal to 0.80, specificity 96.2% for fractional flow reserve greater than 0.80). The hybrid method would have avoided the need to use a hyperemic agent in 65.1% of this patient population. Patients in ADVISE II were recruited from more than 40 centres in the United States and Europe, and all procedures were performed with operators blinded to the instant wave-free ratio values which were calculated offline at an independent core lab in Rotterdam, the Netherlands.

CleanerXT Rotational Thrombectomy System launched in the USA

On 6 May 2014, Argon Medical Devices announced that the company has begun marketing the CleanerXT Rotational Thrombectomy System as a new addition to the Cleaner family of dialysis products. With increased power and torque for cleaning wall-adherent thrombus, and the ability to be introduced through a 6F sheath, CleanerXT combines torque with trackability. Its innovative sinusoidal wire design is radiopaque and conforms to varying lumen diameters, actively cleaning wall-adherent thrombus.

Argon introduced CleanerXT at the 2014 Society of Interventional Radiology meeting in San Diego, USA.

"We continuously look at ways to improve our product offerings so that physicians can provide safe and effective therapy to their patients," stated George Leondis, president of Argon Medical Devices. "CleanerXT provides a tremendous combination of power and minimal invasiveness. Among wall-contacting thrombectomy devices, CleanerXT provides physicians an unmatched ability to effectively macerate wall-adherent thrombus on a 6F device platform."

The CleanerXT Rotational Thrombectomy System was designed by Rex Medical for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

Industry News

Lombard Medical releases results for 2014 first quarter

Lombard Medical has announced summary financial results for the first quarter ended 31 March 2014. Global sales of the company's Aorfix stent graft for the endovascular aortic repair of abdominal aortic aneurysms grew 104% to US$2 million compared with UU$1 million in the first quarter of 2013.

In the United States, where Aorfix was formally launched in November 2013, sales grew 72% sequentially to US$0.5 million in the first quarter as compared to US$0.3 million in the 2013 fourth quarter.

In the main European markets, sales grew 59% to US$1.1 million compared with US$0.7 million in the first quarter of 2013, with growth being driven by UK and Germany sales.

Sales in the rest-of-world distributor markets grew 44% to US$0.4 million from US$0.3 million in the first quarter of 2013.

Total sales grew 64% to US$2 million compared with US$1.3 million in the first quarter of 2013.

According to Lombard, the lower total growth figure reflected the divestment of the company's OEM business in December 2013. Sales from this business were US$0.3 million in the first quarter of 2013.

Net loss for the first quarter of 2014 was US$6.9 million, compared to US$3 million in the first quarter of 2013. The increased loss was principally due to on-going investments in a US-based operation, commercial infrastructure, direct sales force and training activities.

Cash and cash equivalents at 31 March 2014 were US$33.4 million, compared to US$40.9 million at 31 December 2013. Proceeds from the US initial public offering (IPO) on 25 April 2014, after expenses will add approximately US$48 million of cash in the second quarter of 2014.

"It is clear that the 2013 FDA approval for Aorfix is having a positive effect on our international business, and our launch strategy in the US is showing early success as physicians begin to appreciate the clinical benefits of using Aorfix in patients with tortuous AAA anatomy," said Simon Hubbert, CEO of Lombard Medical. "We anticipate acceleration in adoption of Aorfix for the treatment of both highly angulated and less complex aneurysms as we continue to grow our direct sales teams."

TriVascular announces the closing of its initial public offering

On 22 April 2014, TriVascular Technologies, manufacturer of the Ovation Prime Abdominal Stent Graft System, announced the closing of its initial public offering of 7,475,000 shares of its common stock at a public offering price of US$12.00 per share, including 975,000 shares sold pursuant to the underwriter's option to purchase additional shares. The company's shares began trading on The NASDAQ Global Select Market on 16 April 2014 under the ticker symbol "TRIV".

JP Morgan Securities LLC and Credit Suisse Securities (USA) LLC acted as joint book-running managers for the offering. Canaccord Genuity Inc and Stifel, Nicolaus & Company, Incorporated acted as co-managers.

A registration statement relating to the securities being sold in this offering was declared effective by the Securities and Exchange Commission on 15 April 2014.

Calendar of events

5–7 June
Vascular Annual Meeting
Boston, USA
Hynes Convention Center
T +1 (312) 334 2300
E vascular@vascularsociety.org
W www.vascularweb.org

8–10 June
MEET Congress
Nice, France
Radisson BLU Hotel
T +33 (0)491 57 19 60
E info@meetcongress.com
W www.meetcongress.com

26–28 June
European Venous Forum
Paris, France
Cap 15
W www.europeanvenousforum.org

26–28 June
VIP—Vascular Interventional Padova Congress
Padova, Italy
Centro Culturale San Gaetano
T +39 049 860 1818
F +39 049 860 2389
E meet@meetandwork.com
W vipcongress2014.org

27–28 June
18th International Expert Symposium on Critical Issues in Aortic Endografting
Malmö, Sweden
T +49 89 1295440
F +49 89 13936704
E info@cong-o.de
W www.critical-issues-congress.com

11–13 September
4rd International Meeting on Aortic Diseases
Liège, Belgium
Crowne Plaza
T +33 (0) 491 57 19 60
W www.chuliege-imaa.be

13–17 September
TCT
Washington DC, USA
Walter **E** Washington Convention Center
W www.tctconference.com

13–17 September
CIRSE
Glasgow, UK
W www.cirse.org

23–26 September
The European Society for Vascular Surgery XXVIII Annual Meeting
Stockholm, Sweden
Waterfront Congress Centre
T +45 2681 6186
E administration@esvs.org
W www.esvs.org

2–5 October
World Federation of Vascular Societies Congress 2014
Stellenbosch, South Africa
W www.wfvscongress2014.co.za

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4. Rödel S G J, Zeebregts C J, Huisman, A B, Geelkerken, R H. Results of the Anaconda™ Endovascular Graft in Abdominal Aortic Aneurysm with a Severe Angulated Infrarenal Neck. J Vasc Surg 2014; Article in press.
5. Data on file at Vascutek.

* The Magnet Accelerated Cannulation is achieved using the Intrinsic Magnet Guidewire and the Contralateral Magnet Guidewire.

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